



DIGITAL ACCESS TO SCHOLARSHIP AT HARVARD

The Effects of False Claims Act Whistleblowers on the Pharmaceutical Industry

The Harvard community has made this article openly available.
[Please share](#) how this access benefits you. Your story matters.

Citation	The Effects of False Claims Act Whistleblowers on the Pharmaceutical Industry (2006 Third Year Paper)
Accessed	February 19, 2015 9:47:02 AM EST
Citable Link	http://nrs.harvard.edu/urn-3:HUL.InstRepos:8965590
Terms of Use	This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA

(Article begins on next page)

Microsoft Word 10.0.6612;

The Effects of False Claims Act Whistleblowers on the Pharmaceutical
Industry

Mark S. Davis

May 2006

Harvard Law School, Class of 2006

Third-Year Paper in Satisfaction of the Food & Drug Law Course

Requirement and the Written Work Requirement

Peter Barton Hutt, Adviser

Abstract

The whistleblower (or “qui tam”) provisions of the False Claims Act allow private citizens to bring suit on behalf of the government against individuals or corporations who have submitted false or fraudulent claims to the government. Under the Act, a whistleblower is entitled to a percentage of the damages or settlement that the government ultimately receives as a result of the lawsuit. The qui tam provisions have been used with increasing frequency in recent years to initiate lawsuits against pharmaceutical manufacturers for fraud that these companies have allegedly committed against federal and state health care programs. This paper attempts to explain the effects that these whistleblower lawsuits have had upon the pharmaceutical industry. This paper also proposes ways that the False Claims Act and government enforcement efforts could be reformed in order to reduce both frivolous qui tam lawsuits and the need for such extensive False Claims Act prosecution.

Introduction

Whistleblowers are employees who expose what they perceive to be the illegal activities of their employers, as well as organizations with which their employers interact, through means other than those designated by the corporation itself. Since 1986, and particularly in the last decade, the United States pharmaceutical industry has been faced with increased costs of litigation and government scrutiny as a result of whistleblowers within the industry.

This paper analyzes the effects that whistleblowers who disclose corporate fraud through the False Claims Act (“FCA”) and related statutes have had upon the pharmaceutical industry and addresses potential areas of reform of the FCA and pharmaceutical business practices. Section I provides a history of the development of the civil FCA and its whistleblower (or “qui tam”) provisions with particular emphasis on the aspects of the whistleblower provisions which are most relevant to the pharmaceutical industry. This section also discusses the Anti-Kickback Act and its interaction with the FCA. Section II describes whistleblowers’ use of the FCA to bring suit against pharmaceutical companies for their roles in alleged forms of fraud against the government through illegal reimbursement claims made by health care providers to Medicare, Medicaid, and state health care programs. Section III analyzes the effects that litigation incited by whistleblowers has had upon the business conduct and general financial status of the pharmaceutical industry and what consequences these changes could hold for consumers of pharmaceuticals. Section IV proposes various reforms that could alleviate the excessive burden of FCA settlement costs that has been imposed upon pharmaceutical companies. These reforms could ultimately benefit the government, industry, and the American public. Section V provides a brief set of closing remarks.

I. HISTORY OF THE WHISTLEBLOWER PROVISIONS OF THE FALSE CLAIMS ACT

The False Claims Act (“FCA”), currently enacted as 31 U.S.C. § 3729-33 (2000), is one of the strongest tools the government possesses for combating fraud against the United States. While the government may bring suit to recover losses from fraud without cooperation from private citizens, the FCA also authorizes private citizens with non-public information relating to the fraud to bring suit on behalf of the government. These whistleblower (or “qui tam”) suits entitle the claimant to receive a percentage of the recovery for the government, that percentage varying depending upon whether or not the government itself intervenes in the suit. By empowering private persons to initiate FCA lawsuits and guaranteeing them a portion of the government’s recovery, the government is able to punish more fraud against the United States than the Department of Justice could on its own. Qui tam suits create a significant financial incentive for whistleblowers to come forward, and they allow the government to avoid diverting resources to litigating fraud claims that are weaker than others but may still ultimately be successful. These same incentives that justify the government’s endorsement of qui tam suits, however, also constitute the reasons to fear that qui tam suits will be abused and lead to excessive litigation.

This section begins with a brief history of the FCA in order to illustrate the strengths and weaknesses of previous incarnations of the Act that allowed for both greater and lesser flexibility for whistleblowers. The discussion then progresses to the current state of the FCA, as defined by the 1986 False Claims Reform Act, and the related aspects of the Anti-Kickback Act.

A. Early History of the False Claims Act

The original False Claims Act was passed in 1863 in response to defense contractor fraud against the Union during the Civil War.¹ Contractors who were paid for muskets instead provided the Union army with boxes of sawdust, and they sometimes resold horses to the Union cavalry multiple times.² In response, the 1863 Act prohibited anyone from knowingly committing or agreeing to commit any fraud against the United States government through the submission of false or fraudulent claims for payment, and it established both civil and criminal punishments for conviction.³ President Abraham Lincoln, frustrated with the Justice Department's handling of the problem, also successfully urged Congress to enact the "qui tam" provisions in the FCA, allowing whistleblowers (known as "relators") to supplement the efforts of the apparently overwhelmed Justice Department.⁴ Whistleblowers who prosecuted their lawsuits to judgment were entitled to one-half of the damages recovered, with the remaining half belonging to the government.⁵ These whistleblowers were liable for all costs incurred in bringing their qui tam suits and had no claims for reimbursement against the United States.⁶

The pertinent provisions of the 1863 Act were reenacted in 1875 as Revised Statutes Sections 3490-3494, 5438.⁷ The Revised Statutes separately codified the civil and criminal provisions of the FCA, creating an independent "Civil False Claims Act" that remains to this day (henceforth, "False Claims Act" and "FCA" refer to only the civil provisions of the FCA).⁸ The substance of the civil aspects of the FCA, however,

¹Act of Mar. 2, 1863, ch. 67, 12 Stat. 696; 132 CONG. REC. 22,339 (Sept. 9, 1986) (statement of Rep. Berman).

²132 CONG. REC. 22,339 (Sept. 9, 1986) (statement of Rep. Berman).

³§§ 1, 3, 12 Stat. at 696-98.

⁴132 CONG. REC. 22,339-40 (Sept. 9, 1986) (statement of Rep. Bedell).

⁵§ 6, 12 Stat. at 698.

⁶*Id.*

⁷ROBERT SALCIDO, FALSE CLAIMS ACT & THE HEALTHCARE INDUSTRY: COUNSELING & LITIGATION 7-9 (1999).

⁸*See* Pamela H. Bucy, *Private Justice*, 76 S. CAL. L. REV., 1, 45 (2002). The primary criminal provisions of the original

remained essentially the same as a result of the reenactment.⁹ Yet despite the financial incentives that the FCA continued to create for the government and private citizens alike, the FCA “fell into disuse” soon after its reenactment.¹⁰

Due to its infrequent usage, the FCA was not amended again until 1943.¹¹ The 1943 amendments to the FCA (referred to henceforth as “the 1943 Act”) were passed in response to a barrage of so-called “parasitic” lawsuits filed starting in the late 1930s by qui tam relators who essentially “revived” the FCA.¹² As it was originally designed, the FCA contained no measures to prevent private individuals from filing qui tam suits based on public information of fraud. As a result, private parties could file “parasitic” civil lawsuits against contractors who were already under criminal indictment by the government based solely on information contained in the criminal indictments or in media reports of those indictments.¹³ While the filing of such lawsuits did fulfill the 1863 Act’s intent of partly shifting the burden of litigating fraud claims from the Justice Department to the public, it failed to reveal undetected fraud against the government, which was the primary goal of the 1863 Act. On the other hand, Attorney General Biddle, who was a major proponent of reform of the FCA qui tam provisions in 1943, was most concerned with the race to the courtroom created by “parasitic” lawsuits. Whenever a criminal indictment under the FCA was returned, the government was forced to make a hasty decision whether to also file a civil action or risk sharing the civil damage rewards

False Claims Act are now codified as amended at 18 U.S.C. §§ 287, 1001 (2000).

⁹See SALCIDO, *supra* note 7, at 7-9.

¹⁰*Id.* at 9.

¹¹See Act of Dec. 23, 1943, ch. 377, 57 Stat. 608. Section 5438 of the 1875 Revised Statutes was repealed in 1909. See Act of Mar. 4, 1909, ch. 321, § 341, 35 Stat. 1153. However, this change to the Revised Statutes was of little import. Section 5438 of the Revised Statutes primarily served to “set forth those acts creating civil liability” under § 3490 of the Revised Statutes, and courts interpreted § 3490 as having incorporated those portions of § 5438 that enumerated actionable violations of § 3490. SALCIDO, *supra* note 7, at 7-8.

¹²SALCIDO, *supra* note 7, at 9.

¹³James B. Helmer, Jr. & Robert Clark Neff, Jr., *War Stories: A History of the Qui Tam Provisions of the False Claims Act, the 1986 Amendments to the False Claims Act, and Their Application in the United States Ex Rel. Gravitt v. General Electric Co. Litigation*, 18 OHIO N.U. L. REV. 35, 38 (1991).

with unhelpful “informers.”¹⁴

The 1943 Act substantially reduced the viability and incentives of filing qui tam lawsuits by requiring that a whistleblower provide original information, reducing the percentage of damages awarded to qui tam relators, and allowing the government more time to decide whether to file a civil action before a whistleblower (with original information) could do so.¹⁵ First, the Act placed a jurisdictional bar on any qui tam lawsuit for fraud if the government had any knowledge of the fraud at the time the suit was filed.¹⁶ This amendment clearly went much further than prohibiting the types of “parasitic” lawsuits based on public information that had provoked the 1943 Act. It also barred lawsuits brought by whistleblowers with original information in regard to fraud of which the government had only minimal knowledge at the time. According to the decisions of some courts, a qui tam suit was even barred under the 1943 Act if the government’s knowledge of the fraud at issue was solely the result of disclosure by the relator himself to the government, as long as the relator had not yet filed a lawsuit at the time of disclosure.¹⁷ Second, the Act mandated that whistleblowers disclose all of their evidence to the government at the time they filed qui tam suits. The government then had sixty days in which to decide whether to prosecute the claim itself or allow the relators to handle the case alone

¹⁴See SALCIDO, *supra* note 7, at 9-10.

¹⁵Although the restrictions placed on qui tam suits by the 1943 Act were severe, they were not as substantial as they might have been. One bill introduced in the House of Representatives early in the debate over reform of the FCA would have eliminated qui tam suits entirely. *See id.* at 10.

¹⁶Act of Dec. 23, 1943, ch. 377, 57 Stat. 608, 608-09.

¹⁷See Helmer & Neff, *supra* note 13, at 40. The case of *Wisconsin v. Dean*, 729 F.2d 1100 (7th Cir. 1984), which some courts have said spurred Congress to later pass the 1986 Reform Act to the FCA, provides an example of how a result so unfair to a qui tam relator could occur under the 1943 Act:

In *Dean*, the State of Wisconsin, acting independently of the federal government, had investigated and uncovered instances of Medicare fraud. The state had disclosed its evidence of fraud to the federal government prior to bringing the action because the Social Security Act required states to report instances of fraud and abuse to the federal government. The United States informed the district court that it did not know of the fraud until Wisconsin’s disclosure. Nonetheless, the Seventh Circuit, reversing the district court, held that the district court lacked subject matter jurisdiction over the plaintiff’s action.

SALCIDO, *supra* note 7, at 20. Hence qui tam relators could not necessarily avoid the jurisdictional bar by choosing not to reveal information to the federal government before filing a qui tam suit; sometimes the relators had no choice but to inform the government first.

(but still on behalf of the United States).¹⁸ Third, whistleblowers were no longer guaranteed one-half of the amount recovered by the government in a qui tam lawsuit.¹⁹ In fact, they were no longer guaranteed any reward at all. Rewards for relators were capped at twenty-five percent of the damages if the government did not take over prosecution of the case and ten percent if the government did intervene, while courts were granted absolute discretionary power to reduce the whistleblowers' recovery to as low as zero.²⁰

The 1943 Act took the most restrictive approach to qui tam lawsuits under the FCA that has existed to date. Indeed, it has been argued that the 1943 Act “virtually eliminated the qui tam suit as an effective weapon in combating fraud upon the United States Government.”²¹ In particular, the design of the qui tam jurisdictional bar provided contractors who had committed fraud against the government with opportunities to avoid prosecution through limited disclosure of their own wrongdoing:

Under this ill-defined jurisdictional bar, contractors could make vague and limited disclosures to government officials which would support a claim of prior government knowledge, thereby discouraging any investigation by the government. Similarly, the 1943 amendments permitted government contractors to take advantage of over-burdened federal agencies by providing a modicum of information to officials who had neither the time nor the resources to investigate and prosecute the fraud. Under the [1943 Act], by taking advantage of these practical realities, unscrupulous contractors could immunize themselves from any qui tam suit.²²

Despite the apparent ineffectiveness of the 1943 Act, however, the FCA was not amended in any significant way between 1943 and 1986, at which point the Act underwent major reforms.²³

¹⁸57 Stat. at 608.

¹⁹57 Stat. at 609.

²⁰*Id.*

²¹Helmer & Neff, *supra* note 13, at 39.

²³In fact, the FCA was only amended once between the 1943 Act and the 1986 Reform Act; technical amendments were made during the recodification of Title 31 of the United States Code in 1982. 132 CONG. REC. 22,335 (Sept. 9, 1986) (statement of Rep. Glickman).

B. The Current False Claims Act: The 1986 Reform Act and Subsequent Amendments

Congress greatly altered the FCA with its passage of the 1986 Reform Act.²⁴ Several factors help to explain why Congress chose to make substantial amendments to the FCA in 1986 after taking no action for so many years. First, Congress viewed the 1943 Act as simply too weak to sufficiently deter fraud against the government.²⁵ Some members of Congress felt this weakness had become an immediate problem due to “the recent indications of massive procurement abuses occurring in the . . . military buildup” of the 1980s.²⁶ Second, recent case law had illustrated some of the unusual consequences of the broad qui tam jurisdictional bar, and these consequences threatened to further undermine the value of the qui tam provisions.²⁷ In addition, Congress hoped to address the continuing disagreement between federal appeals courts as to the appropriate intent standard to apply under the 1943 Act.²⁸

The new formulation of the FCA reestablished strong financial incentives for qui tam relators to come forward with information of fraud against the government, while also increasing the overall penalties for defendants (and hence increasing the government’s FCA damages as well). The 1986 Act also created remedies for FCA whistleblowers who faced retaliation from their employers, and it defined an intent standard that worked to the detriment of defendants in FCA lawsuits. In total, the Reform Act created the pro-whistleblower FCA that exists today, and it established the whistleblower protections necessary for the remarkable increase in qui tam suits over the last decade. While the Reform Act amended the FCA in many ways, knowledge

²⁴False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153 (codified as amended at 31 U.S.C. §§ 3729-33 (2000)). The 1986 Act was also sometimes referred to as the “1986 Reform Act,” as it is likewise referred to in this paper.

²⁵See SALCIDO, *supra* note 7, at 21.

²⁶132 CONG. REC. 22,336 (Sept. 9, 1986) (statement of Rep. Brooks); *see also* 132 CONG. REC. 22,335 (Sept. 9, 1986) (statement of Rep. Glickman, citing the growing deficit as a justification for reforming the FCA to make it a “workable law”).

²⁷See, *e.g.*, *supra* note 17.

²⁸See SALCIDO, *supra* note 7, at 21.

of only a few of these changes is particularly essential to understand the increase in qui tam suits against pharmaceutical companies after 1986.

First, the Reform Act increased the civil penalties for false claims for the first time since the creation of the FCA in 1863. Between 1863 and 1986, the civil penalty remained two thousand dollars per false claim.²⁹ Congress, based on the testimony of several witnesses during legislative hearings, determined that its failure to adjust the penalties upward during this period had rendered the monetary penalties “no longer a serious deterrent to the filing of false claims.”³⁰ Accordingly, Congress raised the penalties to a minimum of \$5,000 and a maximum of \$10,000 per false claim.³¹ For the same purposes, the Reform Act entitled the government to receive triple its actual damages caused by the defendant’s false claims;³² previously, the FCA only allowed for double damages.³³ These amendments obviously multiplied the size of the civil rewards that the government could earn through FCA actions, and correspondingly increased qui tam relators’ potential share.

Second, Congress created guaranteed minimum rewards for qui tam relators and raised the percentage caps on qui tam rewards. Now, under the Reform Act, if the government intervenes in a relator’s lawsuit, the relator receives at least 15% and no more than 25% of the court-awarded damages or settlement of the lawsuit.³⁴

If the government does not intervene in a lawsuit, the relator is guaranteed 25% of the proceeds, with a maxi-

²⁹See Act of Mar. 2, 1863, ch. 67, § 3, 12 Stat. 696, 698.

³⁰132 CONG. REC. 22,335 (Sept. 9, 1986) (statement of Rep. Glickman). In order to show how dated this unadjusted \$2,000 penalty was, Rep. Glickman pointed out that the “equivalent of \$2,000 in 1863 would [in 1986] be close to \$18,000.” *Id.*

³¹False Claims Amendments Act of 1986, Pub. L. No. 99-562, sec. 2, § 3729(a), 100 Stat. 3153, 3153 (codified as amended at 31 U.S.C. § 3729(a) (2000)).

³²*Id.*

³³132 CONG. REC. 22,336 (Sept. 9, 1986) (statement of Rep. Brooks).

³⁴Sec. 3, § 3730(d)(1), 100 Stat. at 3156 (codified as amended at 31 U.S.C. § 3730(d)(1) (2000)). The 15% minimum reward for a qui tam relator is contingent upon the court’s finding that the relator’s contribution to the prosecution of the lawsuit does not consist primarily of the contribution of public information. *See id.*

mum share of 30%.³⁵ In either situation, the qui tam relator is also entitled to reasonable expenses incurred in the litigation, as well as attorneys' fees.³⁶ *In the opinion of one Congressman, the new guaranteed minimums created "a critical incentive and reward"* which did not exist under the more restrictive 1943 Act.³⁷

Third, the Reform Act slightly eased the qui tam jurisdictional bar that had made the 1943 Act such a weak tool for combating fraud. Section 3730(e)(3) of the Reform Act applied a jurisdictional bar against qui tam actions "based upon allegations or transactions" already being addressed in a civil or administrative civil money penalty hearing in which the government is a party.³⁸ As written, this provision clearly did not significantly alter the 1943 Act's jurisdictional bar, since it continued to forbid the filing of qui tam lawsuits based on information of which the government already had knowledge, regardless of whether the relator was the government's original source for that information.³⁹

Section 3730(e)(4), however, narrowed the jurisdictional bar on qui tam actions based on public information. Congress's creation of Section 3730(e)(4) represented an effort to prevent the litigation of "parasitic" lawsuits that the 1943 Act originally meant to bar, without undermining legitimate relators' lawsuits as the 1943 Act's "government knowledge" standard did. Specifically, Section 3730(e)(4) barred qui tam actions "based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or [GAO] report, hearing, audit, or investigation, or from the news media,"

³⁵Sec. 3, § 3730(d)(2), 100 Stat. at 3156-57 (codified as amended at 31 U.S.C. § 3730(d)(2) (2000)).

³⁶Sec. 3, § 3730(d), 100 Stat. at 3156-57 (codified as amended at 31 U.S.C. § 3730(d) (2000)).

³⁷132 CONG. REC. 22,339 (Sept. 9, 1986) (statement of Rep. Berman).

³⁸Sec. 3, § 3730(e)(3), 100 Stat. at 3157 (codified as amended at 31 U.S.C. § 3730(e)(3) (2000)).

³⁹The text of § 3730(e)(3) reveals that Congress's intent was to create a broad jurisdictional bar against all qui tam actions based on similar allegations to those alleged in a hearing brought by the government, but not all courts have interpreted the law this way:

The case law construing the provision... has mistakenly viewed it as simply another antiparasitic provision and thus has permitted actions to proceed in which the relator did not usurp the critical facts underlying a governmental proceeding. The proper reading of the provision is that it bars all actions that mirror or are similar to a governmental civil lawsuit or administrative civil money proceeding regardless of whether the lawsuit is public and regardless of whether a relator may qualify as an original source.

SALCIDO, *supra* note 7, at 256-57.

unless the relator was an “original source of the information.”⁴⁰ Section 3730(e)(4)(B) clarified that “original source” referred to “an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action. . . which is based on the information.”⁴¹ Hence the Reform Act continued to bar qui tam lawsuits that were strictly “parasitic,” in that they were based on information that was readily available to the government or upon which the government was already acting. On the other hand, the 1986 amendments altered the 1943 Act to allow in two more categories of whistleblower lawsuits that were frequently not parasitic. The “original source” exception of § 3730(e)(4) eliminated the patently unjust practice of barring qui tam actions brought by relators who provided relevant information to the government before filing a lawsuit. Assuming these “original sources” could establish their status as such, then they no longer would be barred for bringing fraud to the attention of the government (which was, after all, the primary goal of the original qui tam provisions). In addition, by abandoning the broad “government knowledge” standard, the Reform Act permitted relators to bring actions “based upon independent information that the government also happened to possess but upon which it failed to act.”⁴² This reform furthered the FCA’s other major goal: the prosecution of fraud against the government by private parties in order to alleviate an over-burdened Justice Department.

While the Reform Act opened the courts to qui tam suits based on information that was already (at least in part) possessed by the government, the amendments did include an exception that negated the new minimum guaranteed reward for a qui tam relator if his or her information was not helpful enough to the government’s FCA case. Section 3730(d)(1) eliminated the guaranteed minimum and placed a cap of 10% on the qui tam rewards of “those ‘original sources’ who bring cases based on information already publicly

⁴⁰Sec. 3, § 3730(e)(4), 100 Stat. at 3157 (codified as amended at 31 U.S.C. § 3730(e)(4) (2000)).

⁴¹Sec. 3, § 3730(e)(4)(B), 100 Stat. at 3157.

⁴²SALCIDO, *supra* note 7, at 204.

disclosed where only an insignificant amount of that information stemmed from that original source.”⁴³ This exception illustrated that while Congress wanted to strengthen the incentives to provide the government with information of fraud, Congress was only willing to provide large financial rewards to whistleblowers who provided significant assistance to the government.

As a further illustration of Congress’s desire to reward only qui tam relators who assisted in the prevention of fraud against the government, Congress again amended the qui tam provisions in 1988. The 1988 amendment allowed the court trying an FCA action to reduce the qui tam reward of any relator who “planned and initiated” the violation of the FCA that was the basis of the relator’s claim.⁴⁴ In addition, “[i]f the person bringing the action is convicted of criminal conduct arising from his or her role in the violation of [the FCA], that person shall be dismissed from the civil action and shall not receive any share of the proceeds of the action.”⁴⁵ The 1988 amendment thus attempted to prevent employees of the targets of FCA action from being rewarded for their own complicity in false claims.

Fourth, Congress used the 1986 Reform Act to end the conflict between the federal courts’ differing interpretations of the FCA’s intent standard for liability. The Reform Act specified that “no proof of specific intent to defraud is required” for a person to be liable for “knowingly” making or causing to be made false claims.⁴⁶ Instead a person acts “knowingly” with respect to information that a false claim is being made when the person “(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth

⁴³132 CONG. REC. 28,580 (Oct. 3, 1986) (statement of Sen. Grassley, discussing the proposed version of 31 U.S.C. § 3730(d)(1) that was later passed by Congress).

⁴⁴Major Fraud Act of 1988, Pub. L. No. 100-700, sec. 9, §3730(d)(3), 102 Stat. 4631, 4638-39 (codified as amended at 31 U.S.C. § 3730(d)(3) (2000)).

⁴⁵*Id.*

⁴⁶Sec. 2, § 3729(b), 100 Stat. at 3154 (codified as amended at 31 U.S.C. § 3729(b) (2000)).

or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. . . .”⁴⁷

This amendment assured that all FCA defendants would be subject to a more easily-fulfilled intent standard, whereas previously only those unfortunate defendants in particular federal circuits had faced liability without a showing of specific intent to defraud.⁴⁸ Congress did not mince words about why it decided to establish this harsher intent standard:

Given the sorry record of hundreds of millions of dollars in fraudulent claims by Federal contractors, persons and entities doing business with the Government must be made to understand that they have an affirmative obligation to ascertain the truthfulness of the claims they submit. No longer will Federal contractors be able to bury their heads in the sand to insulate themselves from the knowledge a prudent person should have before submitting a claim to the Government. Contractors who ignore or fail to inquire about red flags that should alert them to the fact that false claims are being submitted will be liable for those false claims.⁴⁹

By assigning federal contractors an “affirmative obligation” to prevent false claims from being submitted to the government, Congress made contractors liable for not only unintended fraud by their own employees but also for the fraudulent actions of some parties related to the contractor, such as customers. This low standard for proving intent has significant consequences today for the pharmaceutical industry, who are sometimes found liable for the false claims for Medicare reimbursement made by their customers, which include doctors and hospitals. In general, however, the intent standard created by the Reform Act provided greater opportunities for the government and qui tam relators to succeed in FCA litigation, and hence also encouraged the pursuit of more FCA claims against contractors.

Similarly, the Reform Act clarified that all elements of an FCA claim, including damages, must be proven “by

⁴⁷ *Id.*

⁴⁸ “[T]he majority of courts, prior to the 1986 amendments, ruled that the government must prove that defendants possessed a specific intent to deceive (‘ill will’) in order to establish a violation of the FCA. . . . Conversely, courts within the Seventh, Eighth and Tenth Circuits and the Court of Claims held that an intent to deceive was not necessarily a requisite element of proof under the pre-1986 Act.” SALCIDO, *supra* note 7, at 16-17.

a preponderance of the evidence.”⁵⁰ This clarification was necessary because “some courts, because of the FCA’s possibly penal application, had required that the government prove its case by clear and convincing evidence.”⁵¹ This amendment ensured that FCA claims would be subject to the lower burden of proof typical of a civil claim.

Lastly, the Reform Act added a whistleblower retaliation provision that protects qui tam relators’ employment status if they are involved in qui tam lawsuits. Section 3730(h) provides relief for employees who are “discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer” because of the employees’ “investigation for, initiation of, testimony for, or assistance in” a qui tam action.⁵² Relief under this provision includes reinstatement at the same level of seniority as the employee would have had if not for the employer’s discrimination and two times the employee’s back pay plus interest.⁵³ Prior to the Reform Act, relators had “few legal protections against the crudest forms of reprisals. . . .”⁵⁴ This provision represented yet one more attempt by Congress to incentivize qui tam suits.

The 1986 Reform Act remains essentially the same today.⁵⁵ As a whole, the Reform Act created a FCA forum far more friendly to whistleblowers by guaranteeing the qui tam relators (in most cases) some form of financial

⁵⁰Sec. 5, § 3731(c), 100 Stat. at 3158 (codified as amended at 31 U.S.C. § 3731(c) (2000)).

⁵¹SALCIDO, *supra* note 7, at 329. A congressional proposal to amend the FCA in 1998 would have raised the burden of proof to “clear and convincing evidence,” in an attempt to protect defendants from being found guilty under the FCA for “minor, technical regulatory breaches.” Robert Salcido, *The Government’s Increasing Use of the False Claims Act Against the Health Care Industry*, 24 J. LEGAL MED. 457, 464 (2003) (discussing the Health Care Claims Guidance Act, S. 2007 and H.R. 3523, 105th Cong. (1998)). The amendment had “roughly 180 cosponsors,” but failed to pass. *Id.* at 464-65.

⁵²Sec. 4, § 3730(h), 100 Stat. at 3157-58 (codified as amended at 31 U.S.C. § 3730(h) (2000)).

⁵³*Id.*

⁵⁴132 CONG. REC. 22,340 (Sept. 9, 1986) (statement of Rep. Bedell).

⁵⁵The current FCA is codified at 31 U.S.C. §§ 3729-33 (2000).

reward, allowing more qui tam suits to be heard in court, and making success in a qui tam lawsuit more likely than it had been in most federal circuits. Following a short explanation of the Medicaid/Medicare Anti-Kickback Act and how it has overlapped with the FCA, Section II of this paper will discuss the consequences of this pro-whistleblower form of the FCA on the pharmaceutical industry.

C. The Medicare/Medicaid Anti-Kickback Act as It Relates to False Claims Act Actions

The Medicare/Medicaid Anti-Kickback Act (“Anti-Kickback Act”) is a criminal statute created to prevent health care fraud.⁵⁶ Congress originally passed the Anti-Kickback Act in 1972,⁵⁷ with the rather narrow goal of “outlawing referral activities that most professional organizations had considered to be unethical and activities that led to the inappropriate use of scarce federal funds.”⁵⁸ Since 1972, the Act has been expanded so that it not only forbids the offer or acceptance of “kickback[s] or bribe[s]” or “rebate[s]” to induce referrals for medical treatment that is paid for by a federal health care program,⁵⁹ but now also provides greater deterrence by prohibiting “any remuneration” to induce such referrals.⁶⁰ This broader formulation of the Anti-Kickback Act has in turn been limited by a number of safe harbors that allow individuals or corporations to provide rebates on medical treatment or products under certain circumstances, while at the same time punishments for violations of the Act have been increased.⁶¹

The Anti-Kickback Act exists entirely separately from the FCA, which is a civil statute (rather than a

⁵⁶42 U.S.C. § 1320a-7b (2003) (commonly referred to as the “Medicare/Medicaid Anti-Kickback Act,” or simply the “Anti-Kickback Act”).

⁵⁷See Social Security Amendments of 1972, Pub. L. No. 92-603, sec. 242, §§ 1877, 1909, 86 Stat. 1329, 1419.

⁵⁸Robert Salcido, *Mixing Oil and Water: The Government’s Mistaken Use of the Medicare Anti-Kickback Statute in False Claims Act Prosecutions*, 6 ANN. HEALTH L. 105, 110 (1997).

⁵⁹Sec. 242, § 1877, 86 Stat. 1329, 1419 (1972).

⁶⁰42 U.S.C. § 1320a-7b(b)(2) (2003).

⁶¹See Sec. 242, § 1877, 86 Stat. 1329, 1419 (1972) (stating that conviction of a violation of the Anti-Kickback Act was punishable by fines of up to \$10,000 or imprisonment for up to one year); 42 U.S.C. § 1320a-7b(b)(2) (2003) (stating that conviction of a violation of the Anti-Kickback Act now is punishable by fines of up to \$25,000 or imprisonment for up to five years).

criminal statute, like the Anti-Kickback Act) used to prevent a broader range of false claims against the government. Nonetheless, over the last decade, the Anti-Kickback Act has been used by the government and qui tam relators to establish FCA charges against pharmaceutical companies and to increase the pressure on these companies to settle FCA actions at larger settlement figures. Hence a brief explanation of the provisions of the Anti-Kickback Act is necessary to fully understand the later discussion of FCA actions against pharmaceutical companies.

The Anti-Kickback Act forbids any type of payment, “including any kickback, bribe, or rebate,” that is made “directly or indirectly, overtly or covertly, in cash or in kind to any person” for the purpose of inducing that person “to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program. . . .”⁶² The Act also prohibits such inducements to order goods or services which are reimbursable by a federal health care program, specifically Medicare and Medicaid.⁶³ Parallel provisions likewise prohibit the solicitation or acceptance of such payments.⁶⁴ The Act classifies these offenses as felonies; those convicted are subject to fines up to \$25,000 and imprisonment for up to five years.⁶⁵

To narrow this broad prohibition, the Anti-Kickback Act establishes a number of exceptions as well. The most relevant of these exceptions to pharmaceutical companies allows for discounts on services or products that are subject to reimbursement under Medicare or Medicaid if the price reduction is “properly disclosed and appropriately reflected in the costs claimed” by the recipient of the discount.⁶⁶ The Act also allows the

⁶²42 U.S.C. § 1320a-7b(b)(2).

⁶³42 U.S.C. § 1320a-7b(b)(2)(B).

⁶⁴*See* 42 U.S.C. § 1320a-7b(b)(1).

⁶⁵42 U.S.C. § 1320a-7b(b)(2).

⁶⁶42 U.S.C. § 1320a-7b(b)(3)(A).

Secretary of the Department of Health and Human Services to establish additional exceptions.⁶⁷

The Anti-Kickback Act thus differs from the FCA in three particularly significant ways: “(1) it is a criminal statute, (2) it requires that the violator act in a ‘knowing and willful’ manner, and (3) it does not contain any provisions that would permit a private individual to enforce its provisions.”⁶⁸ Despite these crucial differences between the two statutes, federal prosecutors and qui tam relators have repeatedly based civil FCA charges against defendants on the Anti-Kickback Act. Specifically, those bringing suit often assert that the defendant made claims to Medicare or Medicaid for reimbursement for services or products that were provided to patients due to illegal inducements under the Anti-Kickback Act.⁶⁹

The argument in favor of such a claim is that the inducement makes the reimbursement claim “so tainted as to be a false claim;” the Medicare and Medicaid programs are forced to reimburse a physician or health care provider for products or services that might not have been prescribed if not for the alleged kickback. This tactic allows qui tam relators to effectively bring civil suit for violations of the criminal Anti-Kickback Act without a private right of action under the Act. These claims also allow both the government and relators to bring civil FCA actions that successfully assert that the defendant made or received a kickback under the less stringent intent standard of the FCA, when in some cases the defendant’s actions would not constitute a kickback under the “knowing and willful” intent standard of the criminal Anti-Kickback Act.⁷⁰

Disagreement exists between the federal district courts as to whether the government or qui tam relators should be allowed to predicate FCA actions on violations of the Anti-Kickback Act.⁷¹ Due to many pharma-

⁶⁷See 42 U.S.C. § 1320a-7b(b)(3)(E).

⁶⁸Salcido, *supra* note 58, at 106-07.

⁶⁹See, e.g., *id.* at 126 (describing the claims brought by a qui tam relator in *U.S. ex rel. Pogue v. American Healthcorp, Inc.*, 914 F. Supp. 1507 (M.D. Tenn. 1996)).

⁷⁰See *id.* at 130-33 (arguing that courts should not allow FCA actions based on Anti-Kickback Act violations to proceed to trial due to the difference in intent standards between the two statutes).

⁷¹Alissa M. Nann, Janine Catherine Ashe & Kimberly Hope Levy, *Health Care Fraud*, 42 AM. CRIM. L. REV. 573, 627

ceutical companies' fears of going to trial when FCA claims have been brought against them (a topic which will be discussed in the following section), opportunities for clarification by courts of the interaction between the FCA and the Anti-Kickback Act are rare.

II. False Claims Act Lawsuits Against the Pharmaceutical Industry

The qui tam provisions of the FCA have spawned a number of lawsuits against pharmaceutical manufacturers since the 1986 Reform Act. FCA lawsuits have risen considerably in the last decade, with qui tam relators and intervening federal prosecutors using progressively more creative ways to assert that various types of marketing tactics employed by pharmaceutical companies constitute violations of the FCA.

A. TAP Pharmaceuticals Products Settlement

A case that demonstrates the typical progression of a qui tam suit under the current FCA and the harmful (and possibly unwarranted) effects it may have on a pharmaceutical company and its employees is that of TAP Pharmaceutical Products. The TAP case is significant not only for the size of the settlement (TAP paid more than \$1 billion in total fines as a result of federal and state lawsuits), but also because it was the first settlement by a pharmaceutical manufacturer under the FCA that involved both civil and criminal fines.⁷²

The qui tam suit against TAP was initiated by Douglas Durand, a vice president of sales at the Chicago-based pharmaceutical company from February 1995 to January 1996. A major part of Durand's job was to

(2005); *see also* Salcido, *supra* note 58, at 124-30 (discussing examples of the conflicting precedent in district courts as of 1997 regarding whether the FCA allows plaintiffs, including qui tam relators, to bring FCA actions predicated on violations of the Anti-Kickback Act).

⁷²Jonathan K. Henderson & Quintin Cassady, *Drug Deals in 2006: Cutting Edge Legal and Regulatory Issues in the Pharmaceutical Industry*, 15 ANN. HEALTH L. 107, 114 (2006).

sell Lupron, a drug used to treat prostate cancer. As of 2002, annual sales of Lupron equaled \$800 million, about 25% of TAP's revenues.⁷³ Despite competition from AstraZeneca Pharmaceuticals' competing drug, Zoladex, a less expensive alternative to Lupron, TAP managed to establish Lupron as the top prostate drug on the market, thanks in part to the fact that prostate cancer patients found injecting Lupron to be less painful than injecting Zoladex.⁷⁴

Soon after assuming his position with TAP, however, Durand began to suspect that Lupron's success was being boosted by illegal sales tactics. Through sales trips and a discussion with TAP's finance department, Durand discovered that TAP had given large-screen televisions to a significant number of doctors.⁷⁵ The televisions were one of only a number of items (including VCRs and trips to resorts) that the eventual indictment against TAP alleged were given to doctors as a form of bribe to encourage them to prescribe Lupron over competing drugs.⁷⁶ Durand also found evidence that TAP sales managers were not properly accounting for their Lupron samples, leading him to suspect that a number of samples had been gifted to doctors who could then sell the samples at a profit. Failing to account for even one sample could have resulted in a fine of \$1 million.⁷⁷ When, in August 1995, the TAP sales staff discussed the possibility of paying two-percent "administrative fees" to doctors who prescribed Lupron (a plan later implemented by TAP) and, according to Durand, merely laughed off the possible criminal implications of that course of action, Durand committed to pursuing legal action to guarantee he would not be complicit in any fraud.⁷⁸

⁷³Charles Haddad & Amy Barrett, *A Whistle-Blower Rocks an Industry*, BUS. WK., June 24, 2002, at 126, 126.

⁷⁴Melody Petersen, *Court Papers Depict Scheme in Drug Billing*, N.Y. TIMES, Feb. 20, 2001, at C1. *See also* Shannon P. Duffy, *Pharmaceutical Sales Practices Net \$1.2 Billion in 'Qui Tam' Settlements*, LEGAL INTELLIGENCER, June 23, 2003, at 1 ("Patients preferred Lupron, which is injected into the buttocks, over Zoladex, which is injected with a larger needle into a more sensitive spot, the abdomen. Both drugs serve as alternatives to surgery.").

⁷⁵*See* Lisa Biank Fasig, *Whistle-Blower Wiser, Now - Exposing Medicaid Fraud Costs Up-and-Comer His Career Trajectory*, PROVIDENCE-JOURNAL BULLETIN, Sept. 15, 2002, at F1. Durand claimed that when he asked the finance department how many televisions had been given to doctors, the reply was, "More than there are urologists." *Id.*

⁷⁶Alice Dembner, *Drug Firm to Pay \$875M Fine for Fraud: US Alleges Bribery, Price Manipulation*, BOSTON GLOBE, Oct. 4, 2001, at A13.

⁷⁷*See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 333(b)(2)(B) (2000); *see also* Fasig, *supra* note 75 (citing information obtained from the Food and Drug Administration).

⁷⁸*See* Fasig, *supra* note 75.

The approach that Durand then took to build his case against TAP raises questions as to the societal value of qui tam suits in general. Durand did not quickly resign his position at TAP once he determined that he could not tolerate the company's sales practices; in fact, he did not leave TAP for another five months. Nor is there any evidence that Durand attempted, as a vice president of TAP, to rectify what he perceived as rampant fraud in his company after August 1995. Prior to committing himself in August to the whistleblower option, Durand did implement a plan to base sales managers' bonuses on the percentage of samples for which they accounted in an attempt to minimize the free sample problem.⁷⁹ TAP's decision to abandon this bonus plan after three months, however, seems to have signaled the end of Durand's attempts to combat the fraud himself. Instead, Durand spent his remaining months at TAP gathering evidence of fraud and communicating with an attorney about the possibility of bringing a lawsuit against his employer.⁸⁰ Even after Durand provided his attorney with the evidence he had thus far collected of the alleged fraud and the attorney informed him that he had a chance of bringing a successful qui tam suit against TAP, Durand still stayed at TAP for two more months before accepting a post at Astra Merck in January 1996.⁸¹

In May 1996, Durand filed a civil FCA suit in federal district court. Durand's complaints included the allegation that TAP paid illegal kickbacks to doctors in several ways, such as by granting two-percent administrative fees to doctors for prescribing Lupron.⁸² More importantly, Durand alleged that TAP conspired with doctors to charge Medicare at average wholesale prices for samples of Lupron that the doctors had received from TAP sales managers for free or at a discounted price.⁸³ Although the over-billing itself would

⁷⁹See *id.*

⁸⁰See *id.*; Neil Weinberg, *The Dark Side of Whistleblowing*, FORBES, Mar. 14, 2005, at 90, 96.

⁸¹See Fasig, *supra* note 75.

⁸²As noted previously, the discussion of these administrative fees was the event that triggered Durand's decision to pursue a qui tam suit against TAP.

⁸³See Fasig, *supra* note 75 (stating that Durand's original complaints against TAP included "paying illegal kickbacks to doctors, causing doctors to charge Medicare for free samples of Lupron, and encouraging doctors to overcharge for the drug.").

not benefit TAP, complicity in such over-billing would allow TAP to indirectly bribe doctors into prescribing Lupron instead of AstraZeneca's Zoladex. The bribes would unwittingly be paid by the government through its Medicare reimbursement program. Medicare would reimburse the doctors for the average wholesale price of Lupron doses that they had prescribed, even though the doctors paid far less than the wholesale price for those same doses. Durand also made a related accusation that TAP made public reports of Lupron's average wholesale price in which the price was falsely inflated, thus causing doctors to overcharge Medicare in this sense as well, and consequently making it less expensive for TAP to grant discounts to doctors (since the price was already inflated).⁸⁴ These practices are collectively referred to as "marketing the spread."⁸⁵

Five years later, in the fall of 2001, the US Attorney's Office in Boston finally intervened in Durand's suit. Prior to the government's taking over the case, Durand had cooperated with the government in its own secret investigation of TAP, ultimately feeding 200 pages of information to the federal prosecutor.⁸⁶ In October 2001, soon after the government officially intervened in the suit, TAP pleaded guilty to criminal conspiracy for providing doctors with free samples of Lupron for which Medicare was then billed. The financial settlement that TAP and the government reached was enormous.⁸⁷ TAP paid \$290 million in criminal fines,⁸⁸ and in order to settle the civil FCA claims, TAP paid \$559 million to the federal government and \$25.5 million to state governments.⁸⁹ Durand received 14% of the federal FCA settlement, or \$78 million,⁹⁰ while an unrelated whistleblower who was not as central to the government's case, Dr. Joseph Gerstein, received 3%

⁸⁴See Weinberg, *supra* note 80, at 98.

⁸⁵The strategy of persuading doctors to purchase a drug based on the potential profits to the doctor from Medicare reimbursement at inflated average wholesale prices is commonly referred to as "marketing the spread." Marc J. Scheineson & Shannon Thyme Klinger, *Lessons From Expanded Government Enforcement Efforts Against Drug Companies*, 60 FOOD DRUG L.J. 1, 8 (2005).

⁸⁶Haddad & Barrett, *supra* note 73, at 126.

⁸⁷At the time of the settlement, the total amount of fines was the largest ever paid in a health fraud case. Dembner, *supra* note 76.

⁸⁸The criminal fines against TAP stemmed from its guilty plea for conspiracy (in cooperation with its doctor/customers) to violate the Prescription Drug Marketing Act. See *Top 20 Cases*, The False Claims Act Legal Center, at <http://www.taf.org/top20.htm> (Feb. 6, 2006).

⁸⁹Dembner, *supra* note 76.

⁹⁰Durand earned about \$42 million after subtracting taxes and legal fees. Fasig, *supra* note 75.

of the federal FCA fines, or \$16 million, for himself and his employer.⁹¹ Together these criminal and civil fines “amounted to roughly one year’s worth of Lupron sales in the late 1990s...”⁹² TAP settled for this amount despite the fact that the government estimated that “TAP bilked federal and state medical programs out of \$145 million throughout the 1990s.”⁹³ After adding in TAP’s related \$150 million RICO settlement with patients and private health insurance companies in November 2004, the total payout by TAP to settle lawsuits relating to its sales tactics was over \$1 billion.⁹⁴

Although the corporation agreed to settle with the government, TAP refused to publicly concede that it had engaged in significant illegal behavior. TAP admitted that it gave free samples of Lupron to doctors who themselves received illegal reimbursement from the Medicare program.⁹⁵ TAP’s president stated that the company did not feel that “it ha[d] done anything inappropriate in the way it ha[d] priced or reported pricing to the government.”⁹⁶ TAP instead justified the settlement based on its fear that the alternative was to face even more expensive government reprisal – the federal government could have excluded TAP’s drugs from the Medicare program if TAP had lost at trial.⁹⁷ The legitimacy of this justification is supported by the subsequent criminal trial and acquittal of eight TAP sales managers in 2004. The sales managers were

⁹¹Duffy, *supra* note 74. Gerstein was the medical director of pharmacy programs for the Tufts Health Plan. Zoladex had been chosen as the preferred prostate cancer treatment of Tufts. A TAP employee offered Gerstein tens of thousands of dollars in “educational grants” if he would use his position at Tufts to make Lupron the favored drug of the health plan. Upset at this attempt to bribe him, Gerstein quickly filed a FCA suit. Gerstein ultimately assisted federal prosecutors by recording conversations with TAP employees in which they offered him even more sizeable educational grants. Of the \$16 million qui tam award to Tufts and Gerstein, Gerstein received \$5 million, which amounted to a little over \$1 million after taxes and legal fees. See Tim Bryant, *Whistleblowers Reap Rewards But Suffer Consequences*, TRIBUNE (Port St. Lucie/For Pierce, FL), Aug. 13, 2002, Domestic News; Dembner, *supra* note 76.

⁹²*Settlement Valuations*, PHARMACEUTICAL CORP. COMPLIANCE REP., Mar. 16, 2004.

⁹³Haddad & Barrett, *supra* note 73, at 126.

⁹⁴Bruce Japsen, *TAP’s Bill for Lupron Grows; \$150 Million Deal Covers Civil Suits*, CHI. TRIB., Nov. 30, 2004, at C1. The private insurance companies involved in the settlement claimed that they based their reimbursement to insurance beneficiaries on the same Lupron average wholesale prices (which were allegedly inflated by TAP) as Medicare used. See *id.*

⁹⁵See Weinberg, *supra* note 80, at 98.

⁹⁶Dembner, *supra* note 76.

⁹⁷See *id.*

charged with conspiracy to defraud Medicare and provide illegal kickbacks to doctors. Durand was a crucial witness for the government in the trial, and the defense managed to expose major weaknesses in the evidence that Durand and the government had used to influence TAP to settle back in 2001. As one reporter wrote in regard to the trial:

As the trial of a dozen TAP employees played out last year, defense attorneys poked holes in Durand's claims. Kickbacks he said TAP paid to doctors never happened. Price hikes he had accused the firm of imposing to overcharge Medicare hadn't actually taken place. A fancy conference Durand had described as a way to bribe doctors into selling TAP's drugs was in fact paid for by the attendees themselves.⁹⁸

Specifically, Durand's claims against TAP were all based on conduct in which TAP did in fact engage, but not nearly to the degree that Durand alleged and, in some cases, in ways that did not violate any federal statute. Durand claimed that TAP sales managers did not account for half of their free samples; defense counsel showed that the percentage of unrecorded free samples was much lower.⁹⁹ Durand's lawsuit asserted that the two-percent administrative fees were paid to a number of doctors as kickbacks. Defense counsel provided evidence that only one organization received the fees, and they were legal; the customer "had a legal safe harbor to receive the fees."¹⁰⁰ Perhaps due in part to the apparent overzealousness of the government's key source of information against TAP (whose financial motives under the FCA were revealed during the trial as well), the jury found all of the TAP defendants not guilty.¹⁰¹

B. Analysis of the TAP Case

⁹⁹ See *id.* at 98.

¹⁰⁰ *Id.* (stating that Durand justified his claims in regard to the two-percent "kickbacks" by arguing that TAP had "intended to kick the money back" to other customers).

¹⁰¹ See Robert W. Tarun, *The TAP Pharmaceutical Acquittals*, BUS. CRIMES, Mar. 2005, at 1 (discussing the cross-examination of Durand in which his financial motives and his failure to reform the sales methods of TAP were emphasized by defense counsel).

The TAP settlement “set the standard for future settlements with pharmaceutical manufacturers for fraudulent drug pricing and marketing activities.”¹⁰² Accordingly, both the settlement and the related acquittal of TAP employees inspired a great amount of debate. First, both the pharmaceutical industry and those aware of the TAP case in the general public discussed the wisdom of rewarding whistleblowers under the FCA. In addition, the pharmaceutical industry and members of the legal community questioned the fairness of the government’s use of prosecutorial discretion in cases against pharmaceutical corporations, particularly due to the financial incentives prosecutors’ offices have to extort settlements from corporations.

1. The Whistleblower Rewards in the TAP Case

The circumstances of Durand’s involvement in the TAP investigation and settlement provided ample fodder for criticism of *qui tam* suits in general. While Durand’s strategy of remaining in TAP’s employment furthered the FCA’s primary goal of uncovering potential fraud against the government, one may also argue that his actions simultaneously facilitated the continuation of the fraud for several more months. As a vice president of sales, Durand was specially situated to implement reforms of TAP’s sales practices. Although Durand experienced frustration with at least one reform that he proposed, Durand continued to have a responsibility as a TAP vice president to inform TAP of some of what he perceived to be improper company practices. One episode during Durand’s investigation illustrates how his pursuit of the *qui tam* lawsuit trumped his continuing duty to TAP:

As Ainslie [Durand’s attorney] wooed the feds, Durand put on a show of remaining a team player at TAP. In truth, he was the opposite. When word reached him of a California rep whose tactics were “out of line,” he left the matter to a subordinate to handle. Then he forwarded internal TAP correspondence on the matter to Ainslie.¹⁰³

Corporate executives, such as Durand, are expected to provide a form of oversight in regard to employees

¹⁰²Henderson & Cassady, *supra* note 72, at 114.

under their supervision. If a pharmaceutical company, which is subject to a multitude of complex regulations that govern its sales practices and the use of its products, cannot rely on the devotion of its executives to report violations of these regulations to the company itself due to the financial and legal incentives created by qui tam suits, then the company may have no way of knowing that it needs to take corrective action. In essence, the FCA may actually be helping to perpetuate fraud against the government.

The sheer size of the reward that Durand received raises concerns that corporate employees will pursue the qui tam route at the first sign of fraud. Enticed by the possibility of financial gain that will provide for an early and extravagant retirement, pharmaceutical employees may be quick to neglect their roles in their corporations and gamble on the hope that they will be able to uncover extensive fraud when they catch the first whiff of such fraud.

There is ample reason to believe that Durand's actions in the TAP case were not motivated solely by greed. First, Durand realized he could bring his claim under the False Claims Act only after consulting an attorney, suggesting that he may not have been familiar with the system of rewards under the FCA until after he had been documenting TAP's marketing practices for two months.¹⁰⁴ Durand also expressed surprise that the government's case against TAP resulted in a large settlement. Durand claimed to have anticipated that "the government would demand that TAP cease and desist, and then settle for a nominal amount of money."¹⁰⁵

Second, even after the TAP settlement, Durand did not express the disapproval of the entire pharmaceutical

¹⁰⁴See Haddad & Barrett, *supra* note 73, at 128, 130 (stating that after two months of copying company documents, Durand spoke to his attorney who "urged Durand to sue TAP under the federal whistle-blower program..." Durand's decision to contact the attorney was based on the advice of a former colleague at Merck & Co., Durand's employer before he left for TAP); *see also* Fasig, *supra* note 75 (reporting that "Durand didn't fully understand the law" when he began his investigation of TAP and that he instead had to rely on "advice from friends").

¹⁰⁵Fasig, *supra* note 75. Durand did realize that there was the possibility of financial gain, but his awareness of this incentive was only displayed after speaking with his attorney, and the reward he would have anticipated was probably much smaller than the \$78 million reward he ultimately received. *See* Weinberg, *supra* note 80, at 96 (recounting that Durand sent his attorney a story with the headline "Rugby Laboratories Pays \$7.5 Million to Settle Government VA Fraud Allegations; Former Employee Who Brought Qui Tam Suit Receives \$1.1 Million" to confirm that this was the type of lawsuit his attorney was planning; she said it was).

industry one would expect from a man desperate to retire and “get out of the business.” In fact, Durand continued to have glowing words for Merck & Co., the pharmaceutical corporation by whom Durand was employed up to the time he took a position with TAP.¹⁰⁶ Last, and most importantly, Durand was afraid he might face legal repercussions if he did not pursue some form of legal action against TAP. Durand’s fear of criminal prosecution may have been exaggerated (as evidenced by the acquittal of his co-workers years later on charges that were arguably “trumped-up” due to Durand’s own inaccurate information).¹⁰⁷ Still there is no question that Durand’s desire to obtain legal immunity played a major part in Durand’s decision to pursue legal action against TAP; he was not solely motivated by financial concerns.

The existence of other factors in Durand’s case, however, does not justify discounting the possibility of future qui tam suits being pursued solely for financial gain as a result of Durand’s windfall in this case. Corporate employees facing even less exposure to personal liability for their corporations’ actions may still follow Durand’s track in the hope of winning a jackpot. Durand’s qui tam reward displayed to the country that there is no cap to whistleblower rewards under the FCA. The rapid increase in the number of FCA suits brought by health-care industry employees since the time that Durand began his suit suggests that corporate employees took notice of this fact. The extent of Durand’s reward, and the realization that others may follow Durand’s lead, has led some to propose the institution of hard caps on qui tam rewards rather than percentage caps:

¹⁰⁶See Fasig, *supra* note 75 (quoting Durand as summarizing the Merck culture, of which Durand particularly approved, as “take care of the patients, the profits will follow. . .”).

¹⁰⁷If Durand’s fears of personal legal trouble were excessive, TAP’s indifference to his concerns is at least partly to blame. During one TAP meeting in which a sales manager questioned the legality of their two-percent administrative fees, one employee unwisely joked, “How would Doug look in stripes?” *Id.*

TAP may have deserved to get smacked down by prosecutors, and Durand may have deserved a reward for helping to deliver it. But in other areas the government caps whistleblowers' rewards at sane levels – \$250,000 in customs cases and \$1.6 million in those involving bank fraud. It's an odd law that makes whistleblowers centimillionaires for reporting on bad behavior after silently watching it take place under their noses.¹⁰⁸

Some commentators defend the size of the rewards that relators like Durand stand to receive. Many of these supporters of uncapped rewards point to the professional risks that whistleblowers take when they file a FCA suit and argue that handing out large rewards is the only way to encourage these whistleblowers to come forward.¹⁰⁹ Yet this argument does not explain why rewards cannot be capped at a level far below the \$77 million that Durand received. Supporters also point to the large rewards that the government receives in qui tam suits, particularly considering how large a return the government makes on FCA suits as a whole.¹¹⁰ This argument, however, begs the question: should the government intervene in as many cases as it does, the factor which pressures so many FCA defendants to settle early and creates such a high rate of return for the government in such cases?

2. The Government's Role in the TAP Case

The TAP settlement illustrates the overwhelming power that the government wields over health care companies accused of fraud. The case also demonstrates the incentives that the government and, in particular, federal prosecutors' offices have to prosecute fraud in cases that government attorneys feel will result in settlement. These incentives may win out even if these government attorneys are uncertain whether the defendants are guilty of wrongdoing worthy of punishment.

¹⁰⁹ See, e.g., David Greising, *Think About It: Whistleblowing Not Easy Money*, CHI. TRIB., Oct. 7, 2001, at C1 (arguing that professional and societal pressures make whistleblowing such a costly endeavor that the large reward that Durand received was appropriate).

¹¹⁰ See *id.* (providing an estimate that “the government rakes in \$8 for every \$1 it spends pursuing whistleblower cases,” and noting that “for whistleblowers, no big payoff is guaranteed”).

The weapon the government has at its disposal that garners the most fear and criticism from the pharmaceutical industry is debarment. If the government punishes a pharmaceutical company with debarment, the company is no longer permitted to serve as a Medicare provider or a state health care program provider for a set period of time. In several situations, a company is subject to mandatory exclusion from federal and state health care programs for a period of at least five years.¹¹¹ One of these situations that trigger a company's mandatory exclusion occurs if the company is convicted of a criminal felony for fraud against a state or federal health care program.¹¹² In addition, the Inspector General for the Department of Health and Human Services¹¹³ has the discretion to initiate exclusion proceedings on other grounds as well.¹¹⁴ Together, these provisions for mandatory and discretionary debarment provide the government with a potent threat against pharmaceutical companies accused of violating the FCA. Since a trial for accusations of fraud could lead to mandatory debarment, pharmaceutical companies who are dependent upon revenues from drugs that are popular with Medicare or Medicaid recipients often feel like they have no option but to settle before trial. As one defense attorney who represented a TAP vice president in the TAP criminal trial stated, "A company has no choice – they have to settle no matter how minor their exposure may be because the threat of debarment is so great, even for relatively minor conduct."¹¹⁵

¹¹¹See 42 U.S.C. § 1320a-7(a) (2000); Timothy Stoltzfus Jost & Sharon L. Davies, *The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement*, 51 ALA. L. REV. 239, 248 (1999) (discussing the federal administrative sanctions, including debarment, that the government may or must use to punish government health care providers).

¹¹²Jost & Davies, *supra* note 111, at 261.

¹¹³The Office of the Inspector General ("OIG") holds the primary authority in "protecting the Medicare program and its beneficiaries." Lewis Morris & Gary W. Thompson, *Reflections on the Government's Stick and Carrot Approach to Fighting Health Care Fraud*, 51 ALA. L. REV. 319, 319 (1999). OIG is responsible for "providing leadership and recommending policies designed to promote efficiency and to prevent fraud and abuse in the operation of the federal health care programs." *Id.*

¹¹⁴See Jost & Davies, *supra* note 111, at 248 (stating that the Inspector General has the option of bringing exclusion proceedings based on sixteen other grounds," meaning grounds other than those that lead to mandatory exclusion).

¹¹⁵Leonard Post, *Health Care Fraud Score: Big Fines, Little Jail; Recent Acquittals Spark Criticism That U.S. Fraud Unit Is Overzealous*, NAT'L L. J., July 26, 2004, at 6 (quoting attorney David Stetler, defense counsel who successfully represented a TAP vice president in the TAP criminal trial).

The extent to which the threat of debarment was responsible for TAP's decision to settle with the government remains in dispute. As noted before, TAP's president publicly denied the government's claims that TAP's "pricing and reimbursement policies" were illegal even though, as part of the settlement, TAP pleaded guilty to violating the Prescription Drug Marketing Act on these grounds.¹¹⁶ Instead TAP's president publicly stated that TAP's actual reason for settling the government's claims for such a large amount of money was the company's fear of debarment.¹¹⁷ The federal judge who approved the TAP settlement ordered TAP to cease these apparent assertions that TAP was not guilty. The judge said that he did not "want some p.r. flack saying this is all just a big misunderstanding," referring to the charges against TAP.¹¹⁸ Regardless of the degree to which the possibility of debarment determined TAP's decision to settle, there remains no question that debarment factored heavily in TAP's willingness to settle for such a large figure.

Considering the evidence that was unveiled in the criminal trial of the TAP executives, which undermined the legitimacy of many of the claims against TAP, some industry observers questioned the fairness of granting the government debarment power. In debarment, the government possesses a tool that virtually ensures that a corporation will settle once the government has enough evidence to intervene in an FCA lawsuit. As a result, if a company under investigation is likely to be found guilty on at least one count of fraud, they will feel compelled to settle, but the settlement figure will be boosted by any flimsier fraud charges the government has simultaneously brought against the company. In other words, "[a] company has a legal gun to its head: They can win on 99% of the charges and lose on a relatively minor charge and they bet the company and they bet it the wrong way."¹¹⁹ The threat of debarment is so severe that it has been described as the "death penalty" for pharmaceutical corporations;¹²⁰ the rewards that the government and *qui tam*

¹¹⁶Weinberg, *supra* note 80, at 98; *see also supra* notes 95-97 and accompanying text.

¹¹⁷*See* Weinberg, *supra* note 80, at 98.

¹¹⁸*Id.* (quoting William Young, the U.S. District Court judge who oversaw the settlement).

¹¹⁹Post, *supra* note 115 (quoting David Stetler, an attorney who successfully represented a TAP vice president in the TAP criminal trial).

¹²⁰Patrick Clinton, Editorial, *End Pharma's Death Penalty*, PHARMACEUTICAL EXECUTIVE, Aug. 1, 2004, at 14 (arguing that, unlike the defendants in the TAP criminal trial, TAP itself was forced to settle because it faced potential debarment, which

relators have extracted from the corporations as a result of the debarment threat have been characterized as “the healthcare equivalent of ‘greenmail.’”¹²¹

The problems of debarment are complicated by what some people have termed a “conflict of interest” for the federal prosecutors who oversee the government’s FCA lawsuits.¹²² Since 1996, some of the rewards that a federal prosecutor’s office earns from FCA cases are re-appropriated to the prosecutor’s office, allowing the office to function with greater resources in future cases.¹²³ This budgeting mechanism creates a cycle that continuously increases the advantage of a prosecutor’s office in its cases against corporations: “For several consecutive years the larger enforcement budgets have led to larger settlements, which in turn have funded still larger enforcement budgets.”¹²⁴ The hypocrisy inherent in the aggressive prosecution of companies such as TAP (who are guilty of paying what are only arguably “kickbacks”) by prosecutors’ offices (who have an enormous financial stake in accomplishing large settlements with corporations) is not lost on the pharmaceutical industry:

Because [the Office of the Inspector General] benefits financially from its prosecutions, it has a conflict of interest, one that surely should be obvious to people who have meditated long and hard on how a physician can be corrupted by the gift of a ballpoint pen. Could a doctor be influenced by a kickback? Sure. Could a government official be misled by the prospect of enlarging his department’s budget by millions of dollars? Of course. Prosecutors are only human. It’s one reason we have trials.¹²⁵

Hence the incentives that exist for prosecutors to pursue large settlements with pharmaceutical companies make it uncertain whether the United States can rely upon the existence of “prosecutorial discretion” to ensure that the threat of debarment is not wielded against undeserving corporations.

The TAP settlement thus demonstrates the quandary that faces the target of a whistleblower suit that would have been the equivalent of the death penalty for TAP).

¹²¹Michael D. Lam, *Is Everyone a Target? A New Legal Theory, the Latest Off-label Commotion, Appears Far-Fetched to Some, But Raises a Few Serious Questions. Here’s One*, PHARMACEUTICAL EXECUTIVE, Mar. 1, 2004, at 56 (quoting David Hyman, a professor at the University of Maryland school of law).

¹²²Clinton, *supra* note 120.

¹²³See Weinberg, *supra* note 80, at 92.

¹²⁴*Id.*

contains a number of claims, some with merit and some without. Prosecutors, who have the threat of debarment on their side, have an incentive to intervene, regardless of the meritless whistleblower claims. The targets of the lawsuits have no choice but to settle for a much larger sum than that which is warranted by the company's actual wrongdoing.

C. Other Major Lawsuits Initiated by Whistleblowers Against the Pharmaceutical Industry Under the False Claims Act

The TAP investigation and settlement provides one detailed example of how a qui tam suit progresses against a pharmaceutical company and illustrates some of the benefits and harms that a qui tam suit can impose on the industry and society as a whole. To ascertain the extent to which whistleblower suits under the FCA have impacted the pharmaceutical industry, however, it is useful to look at the circumstances of several of the largest qui tam lawsuits in recent years.¹²⁶

The first qui tam lawsuit that settled for an amount comparable to the TAP case occurred in February

¹²⁶For the opinions of the Department of Justice on the major FCA settlements (including several of the settlements discussed in this section, along with two settlements with Bayer Corporation in 2001 and 2003 for false claims made to the Medicare and Medicaid programs) negotiated by the government with pharmaceutical manufacturers between 2001 and 2005, *see generally Medicaid Issues: Hearing Before the Senate Finance Comm.*, Federal Document Clearing House Congressional Testimony (June 29, 2005) (statement of Thomas J. Coleman, Senior Counsel, Deputy Attorney General, Department of Justice).

1997.¹²⁷ SmithKline Beecham Clinical Laboratories, Inc., doing business as Glaxo SmithKline,¹²⁸ paid more than \$325 million as a settlement to the government for false claims it filed with Medicare, Medicaid, and other state health care agencies.¹²⁹ At the time, the civil settlement was the largest ever in a whistleblower lawsuit.¹³⁰ Of the \$325 million total, approximately \$52 million was split among seven whistleblowers¹³¹ as a qui tam reward.¹³² As in the TAP case, the government alleged that SmithKline gave doctors kickbacks and improperly billed the government, although in this case SmithKline was directly seeking reimbursement for laboratory tests, not drugs.¹³³ Also, even after SmithKline made the settlement with the government, the company still “denied the allegations, saying the violations were unintentional and the result of ambiguities in regulations and guidelines.”¹³⁴ SmithKline’s claim of confusion is very similar to the defensive stance that TAP’s president adopted after his company’s settlement.

While the magnitude of SmithKline’s settlement merely heralded a future concern for the pharmaceutical industry (whereas health care providers had faced the brunt of the whistleblower assault prior to 1997),¹³⁵

¹²⁷This is not to say that there were no sizeable FCA settlement figures prior to 1997, only that there were no FCA settlements with individual pharmaceutical manufacturers that were of roughly similar size to the settlement amount in the TAP case. In fact, in the four years prior to February 1997, clinical laboratories “paid more than \$800 million to settle various Medicare fraud cases.” Marc Meltzer & Julie Knipe Brown, *Company Pays Attention to Whistleblower Now*, PHILA. DAILY NEWS, Feb. 25, 1997, Domestic News (reporting information provided by an attorney for two whistleblowers who were in the midst of a qui tam suit at the time of the article). In addition, if one considers qui tam lawsuits as a whole (meaning lawsuits against all companies, not just those in the pharmaceutical industry) between the 1986 Reform Act and February 1998, the Justice Department collected \$2 billion from whistleblower-initiated actions. Donna Shaw, *Whistle-blower Finds Himself Jobless, Abandoned By Government He Tried to Help*, PHILA. INQUIRER, Feb. 1, 1998.

¹²⁸See *Top 20 Cases*, *supra* note 88, at <http://www.taf.org/top20.htm> (describing briefly the allegations and settlement figures involved in the SmithKline settlement in 1997).

¹²⁹Meltzer & Brown, *supra* note 127.

¹³⁰*Smith Kline Whistleblowers Get \$42.3 Million*, PA. L. WKLY., Apr. 20, 1998, at 2.

¹³¹Meltzer & Brown, *supra* note 127 (stating that Robert Merena, the SmithKline whistleblower who was the subject of the article, would have to share the total qui tam reward with six other whistleblowers).

¹³²The \$52 million was split in uneven proportions among the seven whistleblowers, with the bulk of the reward going to the three primary qui tam relators. Specifically, \$42.3 million was granted entirely to these three main whistleblowers, who were forced to seek a court order before the government would grant them the full qui tam reward. See *Smith Kline Whistleblowers Get \$42.3 Million*, *supra* note 130; Janet Elliott, *Qui Tam Award Could Spark Backlash*, TEX. LAW., Apr. 20, 1998, at 1.

¹³³See *Smith Kline Whistleblowers Get \$42.3 Million*, *supra* note 130.

¹³⁴*Id.*

¹³⁵For brief descriptions of the twenty largest FCA settlements (including those involving pharmaceutical companies as well as health care providers) since passage of the 1986 Reform Act and the circumstances surrounding the related FCA charges,

the TAP settlement in October 2001 actually signaled the beginning of a wave of whistleblower lawsuits targeting pharmaceutical manufacturers.¹³⁶ The first instance of this post-TAP wave of litigation occurred when AstraZeneca PLC, a London-based pharmaceutical manufacturer, agreed to pay \$355 million and pleaded guilty to criminal conspiracy in June 2003.¹³⁷ This amount included \$266 million under the FCA alone.¹³⁸

The government's case against AstraZeneca (which was initiated against Zeneca Group PLC, a corporation that merged into AstraZeneca in 1999)¹³⁹ was rooted in incriminating documents disclosed by Douglas Durand, who was also the primary whistleblower in the TAP Pharmaceuticals case.¹⁴⁰ While investigating the alleged fraudulent actions of TAP, Durand also discovered letters sent back-and-forth between TAP and Zeneca that accused each other of using illegal marketing tactics to sell their competing prostate cancer drugs, Lupron (the TAP drug) and Zoladex (the Zeneca product).¹⁴¹ The government's ensuing investigation led to charges against AstraZeneca very similar to those made against TAP. Federal prosecutors charged that Zeneca gave free samples of Zoladex to an estimated 400 physicians and encouraged the doctors to bill Medicare for the drugs, and they claimed that Zeneca bribed doctors with kickbacks, such as "educational grants."¹⁴² Unlike in the TAP case, however, AstraZeneca took "responsibility for any improper sampling conduct that took place in the mid-1990s" after it settled the charges and assured the public that it had

see *Top 20 Cases*, *supra* note 88, at <http://www.taf.org/top20.htm>.

¹³⁶From 2001 to November 2003, "[s]ix pharmaceutical companies . . . paid a total of \$1.6 billion . . . to settle seven whistleblower lawsuits alleging marketing, Medicare and Medicaid fraud. . . ." *Drug Companies: Have Paid \$1.6B to Settle Whistleblower Suits*, AM. HEALTH LINE, Nov. 6, 2003, Inside the Industry (referring to a statement issued by the organization Taxpayers Against Fraud). All of these lawsuits were filed under the FCA, and the government intervened in all of them as well.

¹³⁷Bruce Japsen, *Drug Giant Guilty in Medicare Sales Fraud: AstraZeneca to Pay \$355 Million Fine*, CHI. TRIB., June 21, 2003, at C1.

¹³⁸*Top 20 Cases*, *supra* note 88, at <http://www.taf.org/top20.htm> (describing briefly the allegations and settlement figures involved in the AstraZeneca settlement).

¹³⁹Fred Biddle, *AstraZeneca Guilty of Felony*, NEWS J. (Wilmington, DE), June 21, 2003, at 12A (explaining that Zeneca merged with Astra in 1999).

¹⁴⁰Japsen, *supra* note 137.

¹⁴¹*See id.*

¹⁴²*See id.*

“taken steps within our new company [AstraZeneca] to prevent such activities from happening again.”¹⁴³ Durand, it should be noted, received an additional \$47.5 million qui tam reward for his lawsuit against AstraZeneca, raising his total reward to approximately \$126 million for his whistleblowing efforts.¹⁴⁴ In May 2004, Pfizer paid \$430 million, \$152 million of which was under the False Claims Act,¹⁴⁵ to settle “criminal and civil charges that it paid doctors to prescribe its epilepsy drug, Neurontin, to patients with ailments that the drug was not federally approved to treat.”¹⁴⁶ The qui tam relator in the case, David Franklin, received a reward of \$26.6 million.¹⁴⁷ Franklin was an adviser for Warner-Lambert, a company purchased by Pfizer in 2000 that had conducted the questionable marketing of Neurontin.¹⁴⁸ Franklin resigned his position at Warner-Lambert in 1996 after only four months with the company due to his disagreement with the ways Warner-Lambert was marketing Neurontin to physicians.¹⁴⁹

The complaints raised by Franklin and later the government about the marketing of Neurontin from 1995 through 2000 again included accusations that the company gave illegal gifts to doctors,¹⁵⁰ but the main complaint was that Warner-Lambert encouraged physicians to prescribe Neurontin for uses that were unapproved by the FDA (or “off-label uses”), including the treatment of bipolar disorder, Lou Gehrig’s disease, and attention deficit disorder, among other things.¹⁵¹ This marketing was targeted by the government because, “[a]lthough doctors are free to prescribe any federally approved drug for whatever use they choose,

¹⁴³*Id.* (quoting a public statement released by AstraZeneca after the settlement).

¹⁴⁴*Id.* (reporting that Durand received \$47.5 million for his role in the AstraZeneca case); *see also* Weinberg, *supra* note 80 (stating that the total qui tam reward to Durand was \$126 million).

¹⁴⁵*Top 20 Cases*, *supra* note 88, at <http://www.taf.org/top20.htm> (stating the amount of Pfizer’s payment that was used specifically to settle the False Claims Act charges).

¹⁴⁶Gardiner Harris, *Pfizer to Pay \$430 Million Over Promoting Drug to Doctors*, N.Y. TIMES, May 14, 2004, at C1.

¹⁴⁷Julie Schmitt, *Whistle-blower Started Scrutiny*, USA TODAY, Aug. 17, 2004, http://www.usatoday.com/money/industries/health/drugs/2004-08-17-whistle_x.htm.

¹⁴⁸Harris, *supra* note 146.

¹⁴⁹Shmitt, *supra* note 147.

¹⁵⁰*See id.* (stating that prosecutors accused Warner-Lambert of paying doctors more than \$250,000 and treating them to fancy dinners to persuade them to prescribe Neurontin for unapproved uses).

¹⁵¹Harris, *supra* note 146 (reporting that Warner-Lambert also promoted Neurontin to treat restless leg syndrome and drug and alcohol withdrawal seizures).

pharmaceutical companies are not allowed to promote drugs for nonapproved purposes.”¹⁵² The prescription of Neurontin for unapproved uses was quite extensive; according to surveys conducted around the time of the May 2004 settlement, “[n]early 90 percent of the drug’s sales continue[d] to be for ailments for which the drug [was] not an approved treatment. . . .”¹⁵³ This marketing behavior fell under the FCA because it encouraged physicians to prescribe Neurontin to patients who should not have been given the drug and who qualified for Medicaid.¹⁵⁴ The Pfizer/Warner-Lambert case thus illustrates how the FCA can restrict the activities of pharmaceutical companies who have not engaged in the typical improper billing schemes for which TAP and other companies have been punished. In fact, many in the industry believe that the marketing of drugs for off-label uses will be the next great catalyst for whistleblower suits against pharmaceutical companies.¹⁵⁵

Only two months later, Schering-Plough paid the government \$345 million, including \$293 million under the FCA, for its fraudulent pricing of Claritin, the company’s popular allergy drug.¹⁵⁶ The qui tam relators, three former employees of ITG, Inc., a subsidiary of Schering-Plough, received a total reward of approximately \$32 million.¹⁵⁷ Perhaps even more significantly, Schering-Plough’s sales division was also excluded from “participation in all federal health care programs for at least five years” due to its criminal plea.¹⁵⁸ Schering-Plough’s illegal conduct was similar to that alleged against TAP – Schering-Plough allegedly gave kickbacks to several HMOs, thus discounting the price of Claritin for these customers, without paying rebates

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ Speakers at a conference of pharmaceutical executives in July 2004 warned that litigation resulting from the marketing of off-label uses was imminent: “Prosecutors and regulators are circling, the executives were told. Would-be whistle-blowers are collecting promotional materials, saving e-mails, taping phone calls – in the hope of sharing in a jackpot settlement.” Daren Fonda & Barbara Kiviat, *Curbing the Drug Marketers; How a Clampdown on Pitching Drugs for Unapproved Uses is Changing the Way Big Pharma Operates*, TIME, July 5, 2004, at 40, 40.

¹⁵⁶ *Top 20 Cases*, *supra* note 88, at <http://www.taf.org/top20.htm> (stating that Schering-Plough paid \$52.5 million in criminal fines, \$117 million for state FCA claims, and \$176 million for federal FCA claims). Schering-Plough paid the criminal fine “for paying a kickback to a customer in exchange for the preferred treatment of Claritin” and hence violating the Anti-Kickback Act. *Schering-Plough to Pay \$345 Million to Resolve Criminal and Civil Liabilities for Illegal Marketing of Claritin*, Department of Justice Documents, July 30, 2004, Justice Department Press Releases.

¹⁵⁷ *Schering-Plough to Pay \$345 Million*, *supra* note 156.

¹⁵⁸ *Id.*

to Medicaid or revising its “best price” charged to Medicaid.¹⁵⁹ Once again, Schering-Plough’s marketing tactics were used to discourage its customers from making Allegra (a less-expensive allergy drug and the main competitor of Claritin) their preferred drug.¹⁶⁰

Just recently, in October 2005, Serono, S.A., a Swiss corporation with subsidiaries in the United States, agreed to pay \$704 million (with \$567 million of the payment attributable to FCA claims) to settle civil and criminal charges related to its marketing of Serostim, a human growth hormone drug used to treat AIDS patients.¹⁶¹ The FCA portion of the settlement was the largest to date by a pharmaceutical manufacturer, eclipsing even the \$559 million paid by TAP.¹⁶² Five whistleblowers split \$51.9 million, which was equal to 17% of the FCA settlement.¹⁶³ In order to compensate for a shrinking demand for Serostim,¹⁶⁴ Serono Labs, a subsidiary of Serono, allegedly engaged in a number of marketing tactics, such as kickbacks to doctors, discounts to pharmacies, and the promotion of Serostim for off-label uses, to boost prescriptions of the drug; these tactics made the prescriptions ineligible for reimbursement, and hence the claims submitted for reimbursement by doctors constituted false claims.¹⁶⁵ As in other cases previously discussed, the civil settlement allowed Serono not to take full responsibility for all of the government’s allegations. In particular, Serono was not forced to acknowledge that it had marketed Serostim for off-label uses.¹⁶⁶

The total amounts recovered by the government in fraud cases against the health care industry as a whole

¹⁵⁹ See *id.*; Daniel Dunaief, *Whistleblowers’ Payday: Schering Plough Execs Divvy Up \$31M for Unearthing Big Fraud*, DAILY NEWS (New York), July 31, 2004, at 13.

¹⁶⁰ See *Schering-Plough to Pay \$345 Million*, *supra* note 156.

¹⁶¹ *Top 20 Cases*, *supra* note 88, at <http://www.taf.org/top20.htm>. Serostim is “used to treat AIDS wasting, a condition involving profound involuntary weight loss in AIDS patients.” *Serono Labs Pleads Guilty to the Illegal Marketing of AIDS Drug, Reports U.S. Attorney; Company to Pay \$136.9 Million Criminal Fine As Part of \$704 Million Global Settlement*, PR NEWswire US, Dec. 15, 2005.

¹⁶² See *Top 20 Cases*, *supra* note 88, at <http://www.taf.org/top20.htm> (listing two settlements made by HCA, a for-profit hospital chain, as the only two FCA settlements made by a company within the health care industry that were larger than the Serono settlement).

¹⁶³ *Health Care Fraud: Judge Approves \$704M Serono Settlement; Company Bribed Doctors to Push Drug; Pleads Guilty to Criminal Conspiracy*, PATRIOT LEDGER (Quincy, MA), Dec. 16, 2005, at 15.

¹⁶⁴ Serostim came to market at about the time as the “AIDS cocktail,” a combination of drugs that slows the progress of the AIDS syndrome, began to curtail the problem of AIDS wasting, the condition that Serostim was intended to combat. The demand for Serostim thus declined dramatically soon after its release. *Serono to Pay \$704 Million for the Illegal Marketing of AIDS Drug*, Department of Justice Documents, Oct. 17, 2005, Justice Department Press Releases.

¹⁶⁵ See *id.*; *Serono Labs Pleads Guilty*, *supra* note 161.

¹⁶⁶ Ross Kerber & Charlie Savage, *\$704M Penalty for Drug Maker*, BOSTON GLOBE, Oct. 18, 2005, at A1.

(and the pharmaceutical industry in particular) since 1996 are staggering. According to the Department of Justice, between 1996 and early 2005 the Medicare Trust Fund recovered over \$4.5 billion from litigation and settlements in regard to health care fraud.¹⁶⁷ More specifically, during that same period, “[p]harmaceutical fraud...resulted in...over \$1.6 billion in equitable relief and penalties.”¹⁶⁸ In the six years prior to June 2005, investigations into drug pricing alone “by the U.S. Department of Justice and state attorneys general...yielded settlements totaling more than \$2 billion.”¹⁶⁹ In addition, regardless of new voluntary compliance guidelines adopted several years ago by pharmaceutical companies (discussed in the next section), qui tam suits against the entire health care industry appear to be increasing: “In fiscal year 2005, ending Sept. 30, the United States recovered \$1.4 billion under the False Claims Act. Of that total, \$1.1 billion is associated with health care fraud, according to recent Department of Justice statistics.”¹⁷⁰ The frequency of qui tam lawsuits is also not likely to decrease in the next few years. As of April 2005, there were “100 or more pending [qui tam] cases involving drugmakers, pharmacy benefit managers, doctors and hospitals.”¹⁷¹

III. The Effects of the Increase in False Claims Act Lawsuits on the Pharmaceutical Industry and Consumers of Pharmaceuticals

The increased scrutiny the government has placed on the marketing practices of pharmaceutical companies, much of it a result of the cooperation between qui tam relators and the government under the FCA, has impacted the way that the industry plans to do business in the future. This new landscape for the

¹⁶⁷ *Rising Tide of Litigation Against Pharma from Govt, States and Whistleblowers*, FDLI Told, PHARMA MARKETLETTER, Apr. 15, 2005.

¹⁶⁸ *Id.*

¹⁶⁹ Guy Boulton, *Scrutiny of Drug Companies Expands*, MILWAUKEE J. SENTINEL, July 10, 2005.

¹⁷⁰ Correy E. Stephenson, *Health Care Whistleblower Suits Are on the Rise*, LAW. WKLY. USA, Nov. 21, 2005.

¹⁷¹ *Rising Tide of Litigation*, *supra* note 167 (reporting the statements of Eugene Thierolf, director of the Department of Justice civil division’s Office of Consumer Litigation).

pharmaceutical industry in turn creates both positive and negative consequences for American consumers of pharmaceuticals. Manufacturers of pharmaceuticals face a new reality in which they must devote greater resources to: (1) educating their employees about complicated federal and state regulations on product sales and drug price reporting; (2) establishing internal compliance programs that monitor the marketing strategies utilized by all of their employees, including their subsidiaries' employees; and (3) ensuring that competing pharmaceutical companies are also complying with statutory and voluntary marketing rules to avoid losing market share to less compliant companies. For many pharmaceutical firms, the costs of paying for previous FCA settlements must also be added to these new expenses, while these same companies attempt to determine how to improve their tarnished image with public investors.

All of these additional expenditures have obvious consequences for the public. The costs of these new or strengthened compliance procedures will be passed onto consumers in the form of higher drug prices and could potentially decrease the amount of money that the industry can devote to research, leading to fewer new drugs being available to consumers. National spending on drugs doubled between 1998 and 2004, with spending reaching \$30.6 billion in 2004.¹⁷² Keeping in mind the extent of the public's dependence on access to pharmaceuticals, it is worth debating whether the elimination of the types of fraud allegedly being committed by the pharmaceutical industry is worth the resulting increase in drug prices paid by consumers.

A. The PhRMA Code

The most prominent example of pharmaceutical companies' new approach to marketing is the commitment

¹⁷²Boulton, *supra* note 169.

by the largest firms in the industry to voluntarily follow the PhRMA Code. The Pharmaceutical Research and Manufacturers of America (“PhRMA”) is an industry group whose members include the largest pharmaceutical research and biotechnology companies.¹⁷³ PhRMA’s stated objective is “to conduct effective advocacy for public policies that encourage discovery of important new medicines for patients by pharmaceutical/biotechnology research companies.”¹⁷⁴ In July 2002, PhRMA adopted the *PhRMA Code on Interactions with Healthcare Professionals*, an updated set of ethical guidelines for PhRMA’s member companies to follow when engaged in the marketing of their products to customers in the health care industry.¹⁷⁵ Compliance with the PhRMA Code is not required of member companies. In response to critics of the value of a voluntary code, PhRMA has “point[ed] out that a mandatory code would probably be illegal.”¹⁷⁶ The early endorsement of the Code by fifteen of the country’s largest pharmaceutical companies, however, has led much of the industry to vow compliance with the Code’s rules, although the speed with which the rules have been phased into the companies’ operations has varied.¹⁷⁷

The PhRMA Code includes primarily guidance on how pharmaceutical companies can prevent their employees from violating the Anti-Kickback Act, the law that has led to a number of criminal fines against PhRMA member companies and that has also been responsible for many of the false claims charges against these same companies. Apparent kickbacks to doctors and health care providers are among the most visible illegal actions that pharmaceutical companies commit, but the rules surrounding what constitutes a kickback or

¹⁷³See *About PhRMA*, PhRMA, at <http://www.phrma.org/about-phrma> (Apr. 6, 2006).

¹⁷⁴*Id.*

¹⁷⁵*PhRMA Code on Interactions with Healthcare Professionals*, PhRMA (2004), available at <http://www.phrma.org/files/PhRMA%20Code.pdf> (stating also that the Code was enacted in 2002 and revised in 2004).

¹⁷⁶Milton Liebman, *Drawing a Line Between Education and Promotion: New Regulations Are Reshaping the Way Pharma Companies Work with the Medical Profession, and Adding a New Level of Complexity to this Fast-Growing Educational Effort*, MED. MARKETING & MEDIA, Aug. 1, 2003, at 44.

¹⁷⁷See *id.* TAP Pharmaceuticals was one of the first companies to adopt the Code in June 2002, only a matter of months after it completed its FCA settlement with the government. *TAP Pharmaceutical Products Among First to Adopt PhRMA Marketing Code of Ethics*, PR NEWswire, June 13, 2002.

bribe have been the greatest source of confusion for the industry.¹⁷⁸ The PhRMA Code attempts to eliminate this confusion by establishing several specific standards for drug marketing.

The PhRMA Code provides a list of rules for compliant companies to follow,¹⁷⁹ followed by a number of specific examples of these rules in practice.¹⁸⁰ The Code requires that informational presentations by industry representatives to customers involve “no entertainment/recreational events” and provide only “modest” meals for those people attending.¹⁸¹ Companies may not pay for health care professionals’ costs of travel, lodging, or other personal expenses for attending educational conferences in which the companies take part.¹⁸² The Code promotes restrictions on the “educational grants” that the government has repeatedly called into question: “Financial assistance for scholarships or other educational funds to permit medical students . . . and other healthcare professionals in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made by the academic or training institution.”¹⁸³ Items less than one hundred dollars that are “primarily for the benefit of patients may be offered to healthcare professionals,” while items of “minimal value,” such as pens or notepads (which may have company or product logos on them) may be offered to healthcare professionals.¹⁸⁴ No items, grants, or scholarships, however, may be provided to a health care professional “in exchange for prescribing products or for a commitment to continue prescribing products.”¹⁸⁵ To discourage companies from reading this last restriction in a narrow and self-serving fashion, the Code provides a general warning: “Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare

¹⁷⁸For example, see the description of the TAP settlement and subsequent criminal trial in Section II.A *supra*.

¹⁷⁹See *PhRMA Code*, *supra* note 175, at 2-21.

¹⁸⁰See *id.* at 22-53.

¹⁸¹*Id.* at 7.

¹⁸²See *id.* at 9.

¹⁸³*Id.* at 15.

¹⁸⁴*Id.* at 17.

¹⁸⁵*Id.* at 19.

professional's prescribing practices.”¹⁸⁶

The PhRMA Code's provisions serve several useful purposes, depending on the degree to which member companies choose to comply with them. First and foremost, they establish relatively firm guidelines to which PhRMA members can commit themselves and reduce the conduct that leads to prosecution under the Anti-Kickback statute and FCA. The Office of the Inspector General (OIG), the division of the Department of Health and Human Services that is charged with overseeing the Medicare program,¹⁸⁷ has given qualified approval to the Code. OIG has confirmed that pharmaceutical companies' compliance with the Code “will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements.”¹⁸⁸ OIG added, however, that Code compliance “will not protect a manufacturer as a matter of law under the anti-kickback statute. . . .”¹⁸⁹ While adherence to the PhRMA Code does not guarantee immunity from prosecution, these guidelines should at least reduce FCA lawsuits against the pharmaceutical industry for kickback violations.

The PhRMA Code also should help to calm the competitive pressure between pharmaceutical companies that leads to many of the questionable marketing tactics that the government attacks. The competition between TAP and AstraZeneca to promote their respective prostate cancer treatments demonstrated how companies, even if they generally follow internal compliance standards on marketing, will feel compelled to adopt riskier marketing tactics if a competitor's illegal (or potentially illegal) tactics have so far gone

¹⁸⁶ *Id.*

¹⁸⁷ See *supra* note 113.

¹⁸⁸ *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23,731, 23,737 (May 5, 2003), available at <http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>.

¹⁸⁹ *Id.*

unquestioned or undetected by the government.¹⁹⁰ PhRMA's creation of several specific standards, which have subsequently been adopted by many of the industry group members, provides companies with greater confidence that their competitors will abstain from illegal marketing strategies. Thus a rivalry between two companies' drugs should now be less likely to escalate into a "bidding war" that includes progressively larger illegal kickbacks.¹⁹¹ In a similar regard, by making the PhRMA Code part of internal corporate policy, a pharmaceutical company can more easily head off demands from physicians and health care providers for kickbacks; although infrequently acknowledged, these recipients of kickbacks also deserve a significant share of the blame for illegal marketing practices.¹⁹²

Lastly, the PhRMA Code's value as a positive publicity tool for the pharmaceutical industry should not be underestimated. The illegal kickbacks that the Code attempts to combat are among the easiest violations for the general public to understand, whereas manipulation of a drug's average wholesale price is not a crime that most of the public has time to fully ascertain. The Code demonstrates to the public and to the government that the industry is taking action to address the problem of kickbacks, and this step could gradually win back the public's confidence in pharmaceutical companies. In addition, if the government and qui tam relators continue to initiate actions against the pharmaceutical industry for "kickbacks" that are not forbidden by the Code, even after OIG has given qualified approval to the Code, the industry may finally be able to pressure the government into clarifying its anti-kickback laws. Alternatively, further FCA actions

¹⁹⁰See *supra* notes 73-74 and accompanying text (discussing the competition between TAP's prostate cancer drug, Lupron, and AstraZeneca's Zoladex).

¹⁹¹Representatives of pharmaceutical companies and industry consultants praised the PhRMA Code most of all for its ability to create "a level playing field" that encourages professionalism and ethical marketing strategies. They even expressed hope that different companies in the industry would see the Code as a call to police each other, since there are so many sales representatives in any one company that self-policing can be extremely difficult. See Warren Ross, *New Rules, New Roles for the Sales Force: Warren Ross Talks with a Panel of Experts About How the New PhRMA Marketing Code is Upsetting the Sales Force Apple Cart*, MED. MARKETING & MEDIA, Nov. 1, 2002, at 38.

¹⁹²See generally *id.* (recounting the frustration voiced by the panel of pharmaceutical company employees with demands traditionally made by some physicians for social and entertainment expenses before they would consider prescribing a company's drug).

against PhRMA members for what appear to be only minor transgressions could sour the American public against the FCA and lead to reform of the Act.

Much of the criticism of the PhRMA Code, outside of the charge that the Code is ineffective because it is voluntary, stems from the fact that the Code “has no provisions for any kind of monitoring, proactive or reactive; there is no complaints procedure for alleged breaches; and there are no sanctions for companies that violate the code.”¹⁹³ This line of criticism, however, overlooks the reality that the PhRMA Code is only one piece of any PhRMA member’s compliance procedures; monitoring and complaints procedures are part of any standard internal compliance program. In addition, while PhRMA lacks the ability to sanction noncompliant members, the government’s prosecutorial authority clearly fills this gap, as illustrated by the numerous FCA actions described previously in this paper. Even excluding federal or state government sanctions, a company still faces consequences if it formally adopts the Code: “Meaningful adoption means incorporation of the Code into written company policy; reflection of it in training materials and other internal communications; periodic auditing of compliance; and, as necessary, discipline and other appropriate responses to noncompliance.”¹⁹⁴ The inclusion of the PhRMA Code in internal compliance programs will be discussed in the next subsection.

B. Internal Compliance Programs

Adherence to the PhRMA Code is only one of the tasks to which pharmaceutical companies’ internal compliance programs have been assigned since the barrage of FCA settlements began in 2002. The government has also ordered the industry to adopt more stringent compliance procedures, threatening sanctions for com-

¹⁹³Joel Lexchin, Commentary, *Voluntary Self-Regulatory Codes: What Should We Expect?*, AMER. J. OF BIOETHICS, 2003, at 49.

¹⁹⁴Richard M. Cooper, *Creating Private-Sector Standards of Conduct*, BUS. CRIMES LAW REP., May 16, 2003, at 1.

panies who fail to do so.

In April 2003, OIG issued the “OIG Compliance Program Guidance for Pharmaceutical Manufacturers.”¹⁹⁵ OIG stresses that this document (“OIG Guidance”) is not itself a compliance program; it is rather “a set of guidelines that pharmaceutical manufacturers should consider when developing and implementing a compliance program or evaluating an existing one.”¹⁹⁶ Hence implementing the recommendations of OIG Guidance is also not mandatory.¹⁹⁷ OIG Guidance recommends the adoption of seven elements that are “fundamental to an effective compliance program.” These elements are:

- (1) Implementing written policies and procedures;
- (2) Designating a compliance officer and compliance committee;
- (3) Conducting effective training and education;
- (4) Developing effective lines of communication;
- (5) Conducting internal monitoring and auditing;
- (6) Enforcing standards through well-publicized disciplinary guidelines; and
- (7) Responding promptly to detected problems and undertaking corrective action.¹⁹⁸

OIG states, however, that these elements were already “widely recognized as fundamental” to any compliance program.¹⁹⁹

OIG Guidance also identifies “three major potential risk areas for pharmaceutical manufacturers: (1) Integrity of data used by state and federal governments to establish payment; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples.”²⁰⁰ The recommendations put forth by OIG Guidance on how to prevent violations in these areas by a pharmaceutical company, however, are primarily broad warnings to avoid practices that have led to FCA charges against companies in the past. For

¹⁹⁵See *OIG Compliance Program Guidance*, *supra* note 188, at 23,731.

¹⁹⁶*Id.*

¹⁹⁷See *id.* (“The contents of this guidance should not be viewed as mandatory or as an exclusive discussion of the advisable elements of a compliance program.”).

¹⁹⁹*Id.*

²⁰⁰*Id.* at 23,732.

instance, OIG Guidance advises that companies may avoid prosecution for kickbacks in the form of discounts to health care providers by familiarizing their sales and marketing employees with the safe harbors under the Anti-Kickback Act.²⁰¹ This recommendation avoids providing a detailed interpretation of how to fall within these safe harbors, maintaining the confusion that pharmaceutical companies have complained has led to alleged violations in the first place.

OIG Guidance does provide a few pieces of substantive advice that companies can use to reform their internal compliance programs. Addressing educational grants, OIG Guidance recommends that “[t]o reduce the risks that a grant program is used improperly to induce or reward product purchases or to market product inappropriately, manufacturers should separate their grant making functions from their sales and marketing functions.”²⁰² To avoid prosecution for “marketing the spread,” a practice of which TAP was accused, OIG states that a company should forbid sales representatives from “promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product.”²⁰³ OIG also warns that by granting sales employees “extraordinary expense accounts” and compensating them with “extraordinary incentive bonuses,” a pharmaceutical manufacturer could create an inference that the “manufacturer intentionally motivated the sales force to induce sales through lavish entertainment or other remuneration.”²⁰⁴

OIG Guidance thus has only minor value to pharmaceutical companies looking for original, substantive guidance on how to structure a new or existing compliance program. The document’s greatest value lies in its approving statements toward the PhRMA Code, yet even in this regard, OIG Guidance equivocates so

²⁰¹ *Id.* at 23,735.

²⁰² *Id.* at 23,735.

²⁰³ *Id.* at 23,737; *see also supra* notes 82-85 and accompanying text.

²⁰⁴ *OIG Compliance Program Guidance, supra* note 188, at 23,739.

greatly that it is difficult to determine how safe any company will be from litigation if it conforms to the Code. As stated previously, compliance with “the minimum PhRMA Code standards,”²⁰⁵ while recommended by OIG Guidance, will not always insulate a company from Anti-Kickback charges.²⁰⁶ This language has been criticized for its ambiguity:

Thus, pharmaceutical manufacturers are expected to train their employees and other agents on the Code, with no basis for confidence that the government will view compliance with the Code as even presumptively adequate with respect to its subject matter. OIG also fails even to address the aspects of the Code that arguably go beyond the requirements of law. By characterizing the Code as stating ‘minimum standards,’ OIG arguably expands the scope of legal prohibitions without any discussion of whether such expansion can be justified, and without any apparent recognition that such expansion discourages the private sector from setting higher standards than the obvious statutory minimum.²⁰⁷

OIG intentionally produced a guidance document that is not too specific, with the hope that it would provide assistance to pharmaceutical companies with a variety of pre-established compliance programs.²⁰⁸ Unfortunately, partly as a result of OIG’s commitment to broadly defining its recommendations, pharmaceutical companies still cannot be certain that they have properly tailored their compliance programs to satisfy OIG.

One of the benefits of the aggressive FCA prosecution of pharmaceutical companies by the Department of Justice and OIG is the compliance guidance that it has spawned. As part of a negotiated settlement with the government on FCA and Anti-Kickback charges, it is typical for a corporation to enter into a “corporate integrity agreement.”²⁰⁹ These agreements are “publicly available for companies to review,” and they “show the elements of monitoring and ongoing compliance activities that the government believes will be effective to keep the particular pharmaceutical manufacturer... from violating the applicable laws, rules,

²⁰⁵ *Id.*

²⁰⁶ *Id.* at 23,737.

²⁰⁸ See *OIG Compliance Program Guidance*, *supra* note 188, at 23,732.

²⁰⁹ Henderson & Cassady, *supra* note 72, at 133.

and regulations.”²¹⁰

One such corporate integrity agreement was formed between Bayer Corporation and the government as part of a settlement in 2001. Bayer paid \$14 million to settle claims under the FCA, initiated in a qui tam lawsuit, that Bayer encouraged doctors to buy its products, rather than those of competitors, by “marketing the spread,” much as TAP allegedly did.²¹¹ Bayer’s requisite integrity agreement committed the corporation to forming an internal compliance program involving many of the elements later outlined by OIG Guidance. Institution of these elements, however, was mandatory, and Bayer was required to report any alterations of its program to OIG.²¹² Bayer was subject to fines and penalties, along with potential debarment from federal health care programs, for “material breach or noncompliance” with the agreement.²¹³ The agreement ordered Bayer to create a compliance committee and appoint an internal compliance officer, as well as establish a code of conduct and internal reporting procedures in which its employees had to be educated, particularly for the purpose of ensuring that its drug prices would henceforth be accurately reported to federal health care programs.²¹⁴ All of these elements of a compliance program were later recommended by OIG Guidance.²¹⁵ More specifically, the agreement obligated Bayer to provide specific numbers of hours of training to its employees on how to comply with federal regulations, and it forbade Bayer from hiring or continuing to employ anyone who was currently subject to sanctions under a federal health care program.²¹⁶

Although corporate integrity agreements do not necessarily clarify the aspects of the FCA and Anti-Kickback Act that have frustrated the pharmaceutical industry over the last decade, they at least provide a more concrete example of the type of compliance program that OIG and the Department of Justice are seeking

²¹⁰*Id.*

²¹¹*Medicaid Issues: Hearing Before the Senate Finance Comm., supra* note 126 (statement of Thomas J. Coleman, Senior Counsel, Deputy Attorney General, Department of Justice). Illustrating that adherence to a corporate integrity agreement will not protect a pharmaceutical manufacturer from FCA liability for acts committed prior to institution of the agreement, Bayer was forced to pay \$257.2 million in 2003 to settle FCA claims for unrelated false claims. *See id.*

²¹²Francis J. Serbaroli, *Feds Targeting Big Pharmaceutical Companies*, N.Y. LAW J., Mar. 30, 2001, Health Law, at 3.

²¹³*Id.*

²¹⁴*See id.*

²¹⁵*See generally OIG Compliance Program Guidance, supra* note 188.

²¹⁶*See* Serbaroli, *supra* note 212.

from pharmaceutical companies.

C. Broader Ramifications of Increased False Claims Act Litigation

The strengthening of pharmaceutical compliance programs, discussed in the previous two subsections, promises to simultaneously alleviate and expand the costs of drugs for Americans who qualify for federal health care programs. The wisdom of the government's increased scrutiny of pharmaceutical companies' sales tactics will depend upon whether the cost savings from FCA prosecutions and compliance agreements outweigh the resultant higher drug prices charged to health care programs and other consumers.

While estimates in regard to fraud are inherently difficult to verify, one source estimates that “fraud and abuse costs the health care system as much as 10% of the more than \$1 trillion spent on health care each year.”²¹⁷ Governmental reports have also concluded that “the Medicare program is paying hundreds of millions of dollars too much for prescription drugs,” as a result simply of manipulation of drugs' average wholesale price.²¹⁸ To the extent that fraud is committed by pharmaceutical manufacturers, the Department of Justice and OIG clearly have a duty to prosecute these companies to recover the taxpayer dollars they have illegally obtained. At least prior to the barrage of lawsuits in 2001, there was evidence to suggest that expanded enforcement efforts were having a positive effect: “In 1998, Medicare costs rose only by 1.5%, the lowest growth rate in the history of the program. During the first six months of FY 1999, the cost of the Medicare program actually dropped \$2.6 billion.”²¹⁹ If such trends continue and are truly a result of enforcement efforts, then prosecution of fraud will allow the government to fund federal health care programs

²¹⁷ *Fraud and Abuse*, 2-8 Treatise on Health Care Law (MB) § 8.27 (2005) (citing Keynote address of Dara Corrigan, Acting Inspector General, at HCCA Fraud and Compliance Forum, September 2003).

²¹⁸ Boulton, *supra* note 169 (referring to statistics provided by three separate inspector general reports prepared for Senate Finance Committee hearings).

²¹⁹ Jost & Davies, *supra* note 111, at 257.

at lower costs to taxpayers. Yet the ability to sustain these reductions in costs will depend upon whether prosecutors and qui tam relators target the most appropriate defendants under the FCA, meaning those pharmaceutical companies actually responsible for committing serious fraud against the government.

Although OIG has obvious incentives to reduce the immediate costs of Medicare and Medicaid, the government must also consider the impact that its enforcement efforts have upon the strength of the pharmaceutical industry. Spending on prescription drugs more than doubled between 1998 and 2004, but Medicaid alone now comprises roughly 15% of the U.S. market for prescription drugs.²²⁰ The growing prominence of the government as a consumer of prescription drugs means that pharmaceutical companies will submit an increasing number of claims to federal health care programs for reimbursement. As a consequence, the pharmaceutical industry will be even more susceptible to FCA liability. By having to devote more of their assets to litigation costs and prevention, pharmaceutical companies are less capable of funding research and development on newer drugs, while facing increased scrutiny and litigation initiated by the government: “Rising costs of risk management and threats of litigation could cause the removal of medically-necessary but risky medicines...”²²¹ The costs of litigation and compliance programs will also be passed on to consumers, including the government, in the form of higher drug prices. If these costs result from unwarranted lawsuits against pharmaceutical companies, rather than lawsuits used to recover funds acquired through *actual* fraud, the industry could ultimately be paralyzed.

IV. Proposals for Reform of THE False claims act AND Government Enforcement efforts

²²⁰Boulton, *supra* note 169.

²²¹*Rising Tide of Litigation Against Pharma*, *supra* note 167.

The increasing frequency of FCA lawsuits against the pharmaceutical industry by qui tam relators has understandably been greeted with differing reactions by the government, the American public, and the pharmaceutical industry. Federal prosecutors and much of the public, who harbor mistrust of the pharmaceutical industry, have celebrated FCA settlements with pharmaceutical companies, viewing these settlements as the recovery of funds improperly taken from the federal government. The pharmaceutical industry, while confessing to having committed some infractions of the FCA, has voiced frustration with the government's enforcement efforts. The industry characterizes many of the FCA charges as, at best, overly aggressive prosecution for a combination of minor or unintentional violations and, at worst, a form of extortion due to the government's superior bargaining position.

Assuming that its goal is the minimization of health care fraud and abuse by the pharmaceutical industry, rather than merely the enrichment of government coffers, the government must take steps to legitimize future FCA settlements with pharmaceutical companies. Proper reform could enable the Department of Justice to demonstrate that it is only engaged in the business of prosecuting fraudulent practices that have led to the theft of federal assets, as opposed to searching for potential large settlements regardless of the defendant companies' culpability. By depriving companies of excuses for their decisions to settle FCA claims, the government will be able to foster greater cooperation with the industry for the purpose of reducing health care fraud. With this goal in mind, this section proposes a number of reforms that Congress and OIG should consider adopting.

(1) Set Caps on Qui Tam Rewards

The 1986 False Claims Reform Act corrected many of the overly restrictive qui tam provisions that characterized the 1943 Act. Whistleblowers allow the government to unearth fraud that would otherwise go undetected and assume the burden of the early stages of false claims investigations. In order to encourage these whistleblowers to come forward with useful information, it was necessary to rewrite the provisions of the 1943 Act that barred qui tam relators from bringing suit with crucial but not “original” information and required these relators to assume the costs of prosecuting on behalf of the government without any guaranteed compensation for their effort.

There is no reason, however, that the current qui tam provisions cannot continue to serve their useful purpose with a reasonable, absolute cap on qui tam rewards in place, at least in cases in which the government intervenes. While this paper does not suggest a particular figure at which this cap should be set, simply contemplating the ramifications of setting a cap, adjusted regularly for inflation, at five million dollars, for example, reveals the viability of an absolute cap. First, it is highly unlikely that an executive of a pharmaceutical company or health care provider for whom five million dollars would not be an exorbitant amount of money would initiate a qui tam lawsuit against his or her corporation. As the previous FCA lawsuits discussed herein have shown, qui tam relators often come from the ranks of lower-level executives and employees. Second, the lower-level executive with access to information useful to an FCA claim who earns a salary in the realm of \$200,000 a year would be equally compensated for a number of years by a five-million-dollar qui tam reward, even accounting for taxes and legal fees.²²² Admittedly, many qui tam

²²²Durand, the primary whistleblower in the TAP Pharmaceuticals case and, for a brief period of time, a TAP sales executive, received a salary of \$140,000 in 1995, along with a potential \$50,000 annual bonus. Haddad & Barrett, *supra* note 73, at 128.

relators no longer feel comfortable working at a corporation against which they have filed a qui tam lawsuit, in spite of the whistleblower protections afforded by the FCA.²²³ In addition, many potential whistleblowers fear they will have difficulty finding a job anywhere in an industry once they have “tattled” on a former employer. The purpose of qui tam rewards, however, is not to provide individuals who possess inside information with an opportunity to achieve early retirement. Their purpose is to create a sufficient incentive to entice whistleblowers to provide information of genuine fraud that the whistleblowers have been unable to rectify by means of their own employment status. A reward equal to a number of years’ worth of salary should be a sufficient incentive (in most cases) to accomplish this objective. Third, as was noted previously, there is precedent for placing much lower caps on whistleblower rewards under other statutes.²²⁴

An absolute cap would provide a number of benefits without compromising the efficacy of the FCA’s qui tam provisions. By having to share less of any settlement or court-ordered damages with whistleblowers, who frequently cannot succeed in a qui tam lawsuit without government intervention, the government will be able to return a higher percentage of these funds to the federal health care programs which were allegedly wronged in the first place. In addition, by no longer offering the potential for outrageously large rewards, like the \$78 million received by the whistleblower in the TAP case,²²⁵ the government will add legitimacy to the settlements it reaches in qui tam cases in which federal prosecutors have intervened. Although rewards capped only by a percentage of the amount recovered by the government have the potential to attract a greater number of qui tam claims, they also have the potential to attract more spurious charges of fraud by whistleblowers:

²²³ See *supra* Section I.B (discussing the whistleblower protections created by the 1986 Reform Act, codified as amended at 31 U.S.C. § 3730(h)).

²²⁴ See *supra* note 108 and accompanying text.

²²⁵ See *supra* note 90 and accompanying text.

When it comes to a private bounty system...success should not be measured by volume alone; instead, a successful system must generate primarily meritorious suits, and weed out frivolous ones. To achieve this goal, the incentives must be generous enough to induce participation by insiders, yet not so tempting as to engender meritless suits.²²⁶

Pharmaceutical employees who are angry at their employers for unrelated reasons, or those who anticipate their imminent departure from their jobs, might be willing to provide the government with falsified information to create an FCA claim, simply because the expected value of a qui tam reward is so high. Since the government often relies so much upon the information disclosed by whistleblowers, and because FCA cases so rarely make it to trial, there exists at least a reasonable chance that inaccurate accusations will never be discovered. Even in cases in which the qui tam relators' initial intentions are to accurately report fraud, the possibility of further boosting the total settlement figure may lead the qui tam relator to assert overzealous claims; the revelations made during the trial of TAP employees on criminal charges seem to confirm this risk.²²⁷

Based on this type of cost-benefit analysis, Congress should consider amending the FCA to cap qui tam rewards at a reasonable, absolute level.²²⁸

(2) Limit Applicability of Debarment Measures

The aspect of many FCA settlements that perhaps most detracts from their legitimacy is the threat of debarment.²²⁹ Entering any settlement negotiations on FCA charges, a pharmaceutical company knows that if it allows the charges to proceed to trial and it is convicted of submitting even one false claim to the

²²⁷See *supra* notes 97-101 and accompanying text.

²²⁸Alternatively, one commentator has proposed a more radical revision of the qui tam reward provisions: "It is worth exploring whether a revised bounty system could decrease the numbers of frivolous FCA cases without sacrificing meritorious ones – perhaps along the lines of the Medicare Beneficiary Incentive Program, under which beneficiaries are eligible for 10% or up to \$1,000 of funds recovered as a result of their 'tips' about fraud." Krause, *supra* note 226, at 281-82. The commentator adds that this alternative reward system could remedy the problem of unequal rewards between those relators who are fortunate enough to have the government intervene in their lawsuits (and hence earn the chance to receive an enormous reward) and those relators whose cases do not induce government involvement (and hence frequently earn nothing). See *id.* at 281.

²²⁹See *supra* Section II.B.2.

government, the company could be excluded from all federal health care programs.²³⁰ Since Medicare and Medicaid are such large customers for the pharmaceutical industry, the company is left with no option but to pay a huge settlement, unless the company is absolutely certain of its innocence on all charges. The extent of the company's guilt thus remains a mystery in almost all cases.

At the same time, OIG must retain the ability to exclude noncompliant companies from the health care programs it oversees. Removing debarment as an option for OIG would allow pharmaceutical companies who have repeatedly and blatantly violated federal regulations and committed fraud against Medicare and Medicaid to continue to sell their products to those same programs. Absent the threat of debarment, a pharmaceutical manufacturer might deem the improved market share it would gain through illegal sales tactics to be worth the potential cost of legal fees and court-ordered damages. The Department of Justice could also be overwhelmed by the investigation and litigation costs it would face under such a system.

These conflicting considerations suggest that the best option for Congress is to limit the applicability of permissive debarment so that minor fraud will not be excessively punished. One commentator has presented a number of ways in which this reform could be enacted:

[T]he law could require that permissive exclusion only applies if the violator is found guilty of a certain percentage of the claims in issue as compared with all the claims submitted in a given year. Alternatively, the law could require a set monetary threshold above which permissive exclusion would be applicable. Similarly, the law could require a finding of two separate civil judgments against an individual or entity before that individual or entity could be permissively excluded from the program. The FCA could also provide for certain safe harbors in order to protect "honest" mistakes. For example... the Act could prohibit suits from being brought against individuals who "reasonably" relied on erroneous governmental advice.²³¹

The creation of any or all of these amendments would help to create a fairer bargaining scenario between the

²³⁰Raegan A. McClain, *The Government, the Legislature and the Judiciary – Working Towards Remediating the Problems with the Civil False Claims Act: Where Do We Go From Here?*, 10 ANN. HEALTH L. 191, 241 (2001).

government and pharmaceutical companies who are FCA defendants.²³² The manufacturers will be able to litigate the charges against them that they believe to be meritless without fear of debarment on account of minor violations of the FCA. The government will continue to be able to collect damages for fraud actually committed by these companies. The government will also retain the right to exclude from federal health care programs those companies who have committed significant fraud against the government, meaning that the Department of Justice will still be able to force many settlements with defendants and hence litigation costs will not spiral out of control. Although these revisions of debarment rules would weaken a powerful bargaining tool that the government possesses in FCA prosecutions, reform is necessary to ensure that future settlements between the Department of Justice and the pharmaceutical industry more accurately reflect the actual extent of defendants' FCA violations.

(3) Raise the Burden of Proof on FCA Claims that Are Contingent Upon a Finding that an Illegal Kickback Occurred

Qui tam relators and the government continue to initiate lawsuits against pharmaceutical manufacturers that are based on violations of the Anti-Kickback Act.²³³ Specifically, these claims rest on the argument that physicians or health care providers were induced, by kickbacks from manufacturers, to prescribe drugs that they otherwise would not have prescribed and then submitted claims to the government for reimbursement for these prescriptions. The ability of qui tam relators to effectively sue a company for violations of a criminal

²³²An additional option for reform would be to permit "an informal means of expedited appeal" through the Department of Justice in situations in which a company "believes that it is being unfairly subjected to an abusive settlement demand or to the threat of unwarranted prosecution." Jost & Davies, *supra* note 111, at 316 (suggesting reforms that would lessen the burden of FCA litigation on health care providers but that are equally relevant to pharmaceutical manufacturers).

²³³*See, e.g., supra* note 165 and accompanying text.

statute with no private right of action is certainly troubling in a constitutional sense.²³⁴ The greater practical problem, however, is that plaintiffs can prevail on FCA claims which hinge on a finding that a kickback was paid without meeting the higher burden of proof required by the Anti-Kickback Act.²³⁵ Courts have had few opportunities to address this statutory conflict, due to pharmaceutical companies' fear of going to trial in FCA cases, and the precedent that does exist is in disagreement.²³⁶

Congress should consider stepping in to the void that the courts have left by raising the burden of proof under the FCA for claims that are contingent upon a showing that a defendant violated the Anti-Kickback Act. In such situations, an FCA plaintiff should have to make an initial showing that the defendant violated the Anti-Kickback Act under the "knowing and willful" standard typical of criminal statutes; only then will the plaintiff be able to meet its burden for showing that a false claim was submitted by the defendant. This reform would prevent qui tam relators and the government from manipulating a civil statute in order to simplify what are effectively criminal prosecutions.

(4) Provide Stronger Guidance to the Pharmaceutical Industry Through OIG

To ensure greater compliance by pharmaceutical companies with federal statutes and regulations, OIG must provide these companies with more substantive guidance on how to comply with OIG's interpretations of these rules. Thus far, OIG's recommendations, as embodied in OIG Guidance, have been so vague and non-committal that it seems as if full compliance is never possible. OIG's current approach has the potential to stunt the growth of companies who overly restrict their marketing tactics (relative to their competitors) in an attempt to ensure compliance; these companies will be punished for trying to cooperate with what they

²³⁴See Salcido, *supra* note 58, at 106-08.

²³⁵See *supra* Section I.C.

²³⁶See *supra* note 71 and accompanying text.

mistakenly perceive to be OIG's wishes. In short, "[t]he law deters a particular form of wrongdoing most effectively when it prohibits it in clear terms," and hence OIG has a responsibility to better communicate its expectations for pharmaceutical companies' compliance programs.²³⁷

Most importantly, OIG needs to clarify the extent to which compliance with the PhRMA Code, already adopted by many of the largest pharmaceutical companies, will suffice to satisfy compliance with federal regulations:

OIG ought to make some effort to provide more useful criteria for distinguishing unlawful from lawful arrangements so as not to chill the latter. If it thinks the PhRMA Code inadequate, it should, in the interest of increasing voluntary compliance, suggest ways the Code can be improved, particularly because the Code is likely to become the industry standard. On subject matters as to which it views the Code as inadequate, it should state that conduct undertaken in good faith in compliance with the Code will be treated as at least presumptively lawful. In the end, OIG is likely to achieve a much greater degree of actual prevention of the kinds of conduct the statute is directed against by using and helping to improve private codes such as PhRMA's than by inadvertently discouraging them.²³⁸

Greater clarity from OIG would not only allow the government to reduce the pharmaceutical marketing conduct that the government considers unacceptable. By gradually stripping the industry of its ability to blame settlements on confusion created by unhelpful guidance from the government, OIG's improved recommendations would also increase the apparent fairness of future FCA settlements that the government reaches with members of the pharmaceutical industry.

V. CONCLUSION

The recent rise in the number of qui tam lawsuits initiated against the pharmaceutical industry under the FCA has revealed both the benefits and the costs of offering large rewards for whistleblowing. By allowing whistleblowers with a huge financial incentive to be coupled with the bargaining power of government

²³⁷Krause, *supra* note 226, at 280.

prosecutors, Congress runs the risk of allowing the anti-fraud FCA to instead create more fraud through false charges against defendants. Only by limiting the whistleblowers' financial incentives and the government's power to extort large settlements will Congress be able to ensure that the FCA is serving its intended purpose. OIG likewise must take action to clarify its interpretation of federal statutes and regulations so that FCA prosecutions do not become merely a money-making endeavor for the government and whistleblowers, but rather help lead to a significant reduction in health care fraud.